



(11) **EP 3 456 239 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
**20.03.2019 Bulletin 2019/12**

(51) Int Cl.:  
**A61B 1/12** (2006.01) **A61L 2/18** (2006.01)  
**A61L 2/24** (2006.01)

(21) Application number: **18194289.7**

(22) Date of filing: **13.09.2018**

(84) Designated Contracting States:  
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO  
PL PT RO RS SE SI SK SM TR**  
Designated Extension States:  
**BA ME**  
Designated Validation States:  
**KH MA MD TN**

(71) Applicant: **Ethicon, Incorporated**  
**Somerville, NJ 08876 (US)**

(72) Inventor: **YANG, Sungwook**  
**Irvine, CA 92618 (US)**

(74) Representative: **Small, Gary James**  
**Carpmaels & Ransford LLP**  
**One Southampton Row**  
**London WC1B 5HA (GB)**

(30) Priority: **14.09.2017 US 201715704276**

(54) **APPARATUS AND METHOD TO REPEATEDLY FILL AND PURGE CHANNELS OF ENDOSCOPE**

(57) A medical device reprocessor is operable to perform a method of cleaning an internal channel of a medical device. The method entails activating a first pump to deliver a detergent to the internal channel for a first predetermined duration, activating a second pump to deliver water to the internal channel to rinse out the detergent for a second predetermined duration, and activating a third pump to deliver pressurized air to the internal channel to purge out the water or detergent contained within

the internal channel for a third predetermined duration. Subsequently, the method involves activating a fourth pump to deliver a predetermined volume of disinfectant to the internal channel, and reactivating the third pump to deliver pressurized air to purge out the disinfectant into a chamber. The method repeats filling the internal channel with detergent, water and disinfectant and the subsequent purging of the internal channel with pressurized air.

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**Description****BACKGROUND**

**[0001]** The below discussion relates to the reprocessing (i.e., decontamination) of endoscopes and other instruments that are used in medical procedures. In particular, the below discussion relates to an apparatus and a method that may be used to reprocess a medical device such as an endoscope after the medical device has been used in a first medical procedure, such that the medical device may be safely used in a subsequent medical procedure. While the below discussion will speak mainly in terms of an endoscope, it should be understood that the discussion may also equally apply to certain other medical devices.

**[0002]** An endoscope may have one or more working channels or lumens extending along at least a portion of the length of the endoscope. Such channels may be configured to provide a pathway for passage of other medical devices, etc., into an anatomical region within a patient. These channels may be difficult to clean and/or disinfect using certain primitive cleaning and/or disinfecting techniques. Thus, the endoscope may be placed in a reprocessing system that is particularly configured to clean endoscopes, including the channels within endoscopes. Such an endoscope reprocessing system may wash and disinfect the endoscope. Such an endoscope reprocessing system may include a basin that is configured to receive the endoscope, with a pump that flows cleaning fluids over the exterior of the endoscope within the basin. The system may also include ports that couple with the working channels of the endoscope and associated pumps that flow cleaning fluids through the working channels of the endoscope. The process executed by such a dedicated endoscope reprocessing system may include a detergent washing cycle, followed by a rinsing cycle, followed by a sterilization or disinfection cycle, followed by another rinsing cycle. The sterilization or disinfection cycle may employ disinfectant solution and water rinses. The process may optionally include an alcohol flush to aid displacement of water. A rinsing cycle may be followed by an air flush for drying and storage.

**[0003]** Examples of systems and methods that may be used to reprocess a used endoscope are described in U.S. Pat. No. 6,986,736, entitled "Automated Endoscope Reprocessor Connection with Integrity Testing," issued January 17, 2006, the disclosure of which is incorporated by reference herein; U.S. Pat. No. 7,479,257, entitled "Automated Endoscope Reprocessor Solution Testing," issued January 20, 2009, the disclosure of which is incorporated by reference herein; U.S. Pat. No. 7,686,761, entitled "Method of Detecting Proper Connection of an Endoscope to an Endoscope Reprocessor," issued March 30, 2010, the disclosure of which is incorporated by reference herein; and U.S. Pat. No. 8,246,909, entitled "Automated Endoscope Reprocessor Germicide Concentration Monitoring System and Method," issued August 21, 2012, the disclosure of which is incorporated by reference herein. An example of a commercially available endoscope reprocessing system is the EVOTECH® Endoscope Cleaner and Reprocessor (ECR) by Advanced Sterilization Products of Irvine, California.

**[0004]** Some versions of reprocessing systems may provide just a single use of a certain volume of disinfectant solution, such that the used volume of disinfectant solution is disposed of after a single use of the volume of disinfectant solution upon completion of the disinfection cycle. Some other versions of reprocessing system may check the concentration level of a used volume of disinfectant solution and either re-use the used disinfectant solution (i.e., if the concentration level is still acceptable) or dispose of the used disinfectant solution (i.e., if the concentration level is no longer acceptable). Examples of versions of reprocessing systems that provide monitoring and re-use of disinfectant solution are disclosed in U.S. Pat. No. 8,246,909, entitled "Automated Endoscope Reprocessor Germicide Concentration Monitoring System and Method," issued August 21, 2012, the disclosure of which is incorporated by reference herein; in U.S. Patent App. No. 15/157,800, entitled "Apparatus and Method for Reprocessing a Medical Device," filed on May 18, 2016, the disclosure of which is incorporated by reference herein; and in U.S. Patent App. No. 15/157,952, entitled "Apparatus and Method to Measure Concentration of Disinfectant in Medical Device Reprocessing system," filed on May 18, 2016, the disclosure of which is incorporated by reference herein.

**[0005]** While a variety of systems and methods have been made and used to reprocess medical devices, it is believed that no one prior to the inventor(s) has made or used the technology as described herein.

**BRIEF DESCRIPTION OF THE DRAWINGS**

**[0006]** It is believed the present invention will be better understood from the following description of certain examples taken in conjunction with the accompanying drawings, in which like reference numerals identify the same elements and in which:

FIG. 1 depicts a front elevational view of an exemplary reprocessing system;

FIG. 2 depicts a schematic diagram of the reprocessing system of FIG. 1, with only a single decontamination basin shown for clarity;

FIG. 3 depicts a cross-sectional side view of proximal and distal portions of an endoscope that may be decontaminated using the reprocessing system of FIG. 1;

FIG. 4 depicts a schematic diagram of a second exemplary reprocessing system;

FIG. 5 depicts a schematic diagram of a third exemplary reprocessing system;

FIG. 6 depicts a partial schematic diagram of an exemplary variation of the reprocessing systems of FIGS. 4-5;

FIG. 7 depicts a flow diagram illustrating an exemplary reprocessing method utilized by the reprocessing system of FIG. 6, with the internal channels of an endoscope undergoing a repetitive disinfecting cycle with previously used disinfectant;

FIG. 8 depicts a partial schematic diagram of an exemplary variation of the reprocessing system of FIG. 1; and

FIG. 9 depicts a flow diagram illustrating another exemplary reprocessing method utilized by the reprocessing system of FIG. 8, with the internal channels of an endoscope undergoing a repetitive disinfecting cycle.

**[0007]** The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the invention may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention; it being understood, however, that this invention is not limited to the precise arrangements shown.

## DETAILED DESCRIPTION

**[0008]** The following description of certain examples of the technology should not be used to limit its scope. Other examples, features, aspects, embodiments, and advantages of the technology will become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the technology. As will be realized, the technology described herein is capable of other different and obvious aspects, all without departing from the technology. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

**[0009]** It is further understood that any one or more of the teachings, expressions, embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The following-described teachings, expressions, embodiments, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those of ordinary skill in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

### I. Exemplary Medical Device Reprocessing Apparatus with Single-Use Disinfectant

**[0010]** FIGS. 1-2 show an exemplary reprocessing system (2) that may be used to decontaminate endoscopes and other medical devices that include channels or lumens formed therethrough. System (2) of this example generally includes a first station (10) and a second station (12). Stations (10, 12) are at least substantially similar in all respects to provide for the decontamination of two different medical devices simultaneously or in series. First and second decontamination basins (14a, 14b) receive the contaminated devices. Each basin (14a, 14b) is selectively sealed by a respective lid (16a, 16b). In the present example, lids (16a, 16b) cooperate with respective basins (14a, 14b) to provide a microbe-blocking relationship to prevent the entrance of environmental microbes into basins (14a, 14b) during decontamination operations. By way of example only, lids (16a, 16b) may include a microbe removal or HEPA air filter formed therein for venting.

**[0011]** A control system (20) includes one or more microcontrollers, such as a programmable logic controller (PLC), for controlling decontamination and user interface operations. Although one control system (20) is shown herein as controlling both decontamination stations (10, 12), those skilled in the art will recognize that each station (10, 12) can include a dedicated control system. A visual display (22) displays decontamination parameters and machine conditions for an operator, and at least one printer (24) prints a hard copy output of the decontamination parameters for a record to be filed or attached to the decontaminated device or its storage packaging. It should be understood that printer (24) is merely optional. In some versions, visual display (22) is combined with a touch screen input device. In addition, or in the alternative, a keypad and/or other user input feature is provided for input of decontamination process parameters

and for machine control. Other visual gauges (26) such as pressure meters and the like provide digital or analog output of decontamination or medical device leak testing data.

**[0012]** FIG. 2 diagrammatically illustrates just one decontamination station (10) of reprocessing system (2), but those skilled in the art will recognize that decontamination station (12) may be configured and operable just like decontamination station (10). It should also be understood that reprocessing system (2) may be provided with just one single decontamination station (10, 12) or more than two decontamination stations (10, 12).

**[0013]** Decontamination basin (14a) receives an endoscope (200) (see FIG. 3) or other medical device therein for decontamination. Any internal channels of endoscope (200) are connected with flush conduits, such as flush lines (30). Each flush line (30) is connected to an outlet of a corresponding pump (32), such that each flush line (30) has a dedicated pump (32) in this example. Pumps (32) of the present example comprise peristaltic pumps that pump fluid, such as liquid and air, through the flush lines (30) and any internal channels of endoscope (200). Alternatively, any other suitable kind of pump(s) may be used. In the present example, pumps (32) can either draw liquid from basin (14a) through a filtered drain and a valve (S1); or draw decontaminated air from an air supply system (36) through a valve (S2). Air supply system (36) of the present example includes a pump (38) and a microbe removal air filter (40) that filters microbes from an incoming air stream.

**[0014]** A pressure switch or sensor (42) is in fluid communication with each flush line (30) for sensing excessive pressure in the flush line. Any excessive pressure or lack of flow sensed may be indicative of a partial or complete blockage (e.g., by bodily tissue or dried bodily fluids) in an endoscope (200) channel to which the relevant flush line (30) is connected. The isolation of each flush line (30) relative to the other flush lines (30) allows the particular blocked channel to be easily identified and isolated, depending upon which sensor (42) senses excessive pressure or lack of flow.

**[0015]** Basin (14a) is in fluid communication with a water source (50), such as a utility or tap water connection including hot and cold inlets, and a mixing valve (52) flowing into a break tank (56). A microbe removal filter (54), such as a 0.2  $\mu\text{m}$  or smaller absolute pore size filter, decontaminates the incoming water, which is delivered into break tank (56) through the air gap to prevent backflow. A sensor (59) monitors liquid levels within basin (14a). An optional water heater (53) can be provided if an appropriate source of hot water is not available. The condition of filter (54) can be monitored by directly monitoring the flow rate of water therethrough or indirectly by monitoring the basin fill time using a float switch or the like. When the flow rate drops below a select threshold, this indicates a partially clogged filter element that requires replacement.

**[0016]** A basin drain (62) drains liquid from basin (14a) through an enlarged helical tube (64) into which elongated portions of endoscope (200) can be inserted. Drain (62) is in fluid communication with a recirculation pump (70) and a drain pump (72). Recirculation pump (70) recirculates liquid from basin drain (62) to a spray nozzle assembly (60), which sprays the liquid into basin (14a) and onto endoscope (200). A coarse screen (71) and a fine screen (73) filter out particles in the recirculating fluid. Drain pump (72) pumps liquid from basin drain (62) to a utility drain (74). A level sensor (76) monitors the flow of liquid from pump (72) to utility drain (74). Pumps (70, 72) can be simultaneously operated such that liquid is sprayed into basin (14a) while basin (14a) is being drained, to encourage the flow of residue out of basin (14a) and off of endoscope (200). Of course, a single pump and a valve assembly could replace dual pumps (70, 72).

**[0017]** An inline heater (80) with temperature sensors (82), upstream of recirculation pump (70), heats the liquid to optimum temperatures for cleaning and/or disinfection. A pressure switch or sensor (84) measures pressure downstream of circulation pump (70). In some variations, a flow sensor is used instead of pressure sensor (84), to measure fluid flow downstream of circulation pump (70). Detergent solution (86) is metered into the flow downstream of circulation pump (70) via a metering pump (88). A float switch (90) indicates the level of detergent (86) available. Disinfectant (92) is metered into the flow upstream of circulation pump (70) via a metering pump (94). To more accurately meter disinfectant (92), pump (94) fills a metering pre-chamber (96) under control of a fluid level switch (98) and control system (20). By way of example only, disinfectant solution (92) may comprise an activated glutaraldehyde salutation, such as CIDEX® Activated Glutaraldehyde Solution by Advanced Sterilization Products of Irvine, California. By way of further example only, disinfectant solution (92) may comprise ortho-phthalaldehyde (OPA), such as CIDEX® ortho-phthalaldehyde solution by Advanced Sterilization Products of Irvine, California. By way of further example only, disinfectant solution (92) may comprise peracetic acid (PAA).

**[0018]** Some endoscopes (200) include a flexible outer housing or sheath surrounding the individual tubular members and the like that form the interior channels and other parts of endoscope (200). This housing defines a closed interior space, which is isolated from patient tissues and fluids during medical procedures. It may be important that the sheath be maintained intact, without cuts or other holes that would allow contamination of the interior space beneath the sheath. Therefore, reprocessing system (2) of the present example includes means for testing the integrity of such a sheath. In particular, an air pump (e.g., pump (38) or another pump (110)) pressurizes the interior space defined by the sheath of endoscope (200) through a conduit (112) and a valve (S5). In the present example, a HEPA or other microbe-removing filter (113) removes microbes from the pressurizing air. A pressure regulator (114) prevents accidental over pressurization of the sheath. Upon full pressurization, valve (S5) is closed and a pressure sensor (116) looks for a drop in pressure in conduit (112), which would indicate the escape of air through the sheath of endoscope (200). A valve (S6) selectively

vents conduit (112) and the sheath of endoscope (200) through an optional filter (118) when the testing procedure is complete. An air buffer (120) smoothes out pulsation of pressure from air pump (110).

**[0019]** In the present example, each station (10, 12) also contains a drip basin (130) and spill sensor (132) to alert the operator to potential leaks.

**[0020]** An alcohol supply (134), controlled by a valve (S3), can supply alcohol to channel pumps (32) after rinsing steps, to assist in removing water from channels (210, 212, 213, 214, 217, 218) of endoscope (200).

**[0021]** Flow rates in lines (30) can be monitored via channel pumps (32) and pressure sensors (42). If one of pressure sensors (42) detects too high a pressure, the associated pump (32) is deactivated. The flow rate of pump (32) and its activated duration time provide a reasonable indication of the flow rate in an associated line (30). These flow rates are monitored during the process to check for blockages in any of the channels of endoscope (200). Alternatively, the decay in the pressure from the time pump (32) cycles off can also be used to estimate the flow rate, with faster decay rates being associated with higher flow rates.

**[0022]** A more accurate measurement of flow rate in an individual channel may be desirable to detect subtler blockages. To that end, a metering tube (136) having a plurality of level indicating sensors (138) fluidly connects to the inputs of channel pumps (32). In some versions, a reference connection is provided at a low point in metering tube (136) and a plurality of sensors (138) are arranged vertically above the reference connection. By passing a current from the reference point through the fluid to sensors (138), it can be determined which sensors (138) are immersed and therefore determine the level within metering tube (136). In addition, or in the alternative, any other suitable components and techniques may be used to sense fluid levels. By shutting valve (S1) and opening a vent valve (S7), channel pumps (32) draw exclusively from metering tube (136). The amount of fluid being drawn can be very accurately determined based upon sensors (138). By running each channel pump (32) in isolation, the flow therethrough can be accurately determined based upon the time and the volume of fluid emptied from metering tube (136).

**[0023]** In addition to the input and output devices described above, all of the electrical and electromechanical devices shown are operatively connected to and controlled by control system (20). Specifically, and without limitation, switches and sensors (42, 59, 76, 84, 90, 98, 114, 116, 132, 136) provide input (I) to microcontroller (28), which controls the cleaning and/or disinfection cycles and other machine operations in accordance therewith. For example, microcontroller (28) includes outputs (O) that are operatively connected to pumps (32, 38, 70, 72, 88, 94, 100, 110), valves (S1, S2, S3, S5, S6, S7), and heater (80) to control these devices for effective cleaning and/or disinfection cycles and other operations.

**[0024]** As shown in FIG. 3, endoscope (200) has a head part (202). Head part (202) includes openings (204, 206) formed therein. During normal use of endoscope (200), an air/water valve (not shown) and a suction valve (not shown) are arranged in openings (204, 206). A flexible shaft (208) is attached to head part (202). A combined air/water channel (210) and a combined suction/biopsy channel (212) are accommodated in shaft (208). A separate air channel (213) and water channel (214) are also arranged in head part (202) and merge into air/water channel (210) at the location of a joining point (216). It will be appreciated that the term "joining point" as used herein refers to an intersecting junction rather than being limited to a geometrical point and, the terms may be used interchangeably. Furthermore, a separate suction channel (217) and biopsy channel (218) are accommodated in head part (202) and merge into suction/biopsy channel (212) at the location of a joining point (220).

**[0025]** In head part (202), air channel (213) and water channel (214) open into opening (204) for the air/water valve (not shown). Suction channel (217) opens into opening (206) for the suction valve (not shown). Furthermore, a flexible feed hose (222) connects to head part (202) and accommodates channels (213', 214', 217'), which are connected to air channel (213), water channel (214), and suction channel (217) via respective openings (204, 206). In practice, feed hose (222) may also be referred to as the light-conductor casing. The mutually connecting air channels (213, 213') will collectively be referred to below as air channel (213). The mutually connecting water channels (214, 214') will collectively be referred to below as water channel (214). The mutually connecting suction channels (217, 217') will collectively be referred to below as suction channel (217). A connection (226) for air channel (213), connections (228, 228a) for water channel (214), and a connection (230) for suction channel (217) are arranged on the end section (224) (also referred to as the light conductor connector) of flexible hose (222). When the connection (226) is in use, connection (228a) is closed off. A connection (232) for biopsy channel (218) is arranged on head part (202).

**[0026]** A channel separator (240) is shown inserted into openings (204, 206). Channel separator (240) comprises a body (242) and plug members (244, 246), which occlude respective openings (204, 206). A coaxial insert (248) on plug member (244) extends inwardly of opening (204) and terminates in an annular flange (250), which occludes a portion of opening (204) to separate channel (213) from channel (214). By connecting lines (30) to openings (226, 228, 228a, 230, 232), liquid for cleaning and disinfection can be flowed through endoscope channels (213, 214, 217, 218) and out of a distal tip (252) of endoscope (200) via channels (210, 212). Channel separator (240) ensures that such liquid flows all the way through endoscope (200) without leaking out of openings (204, 206); and isolates channels (213, 214) from each other so that each channel (213, 214) has its own independent flow path. One of skill in the art will appreciate that various endoscopes having differing arrangements of channels and openings may require modifications to channel

separator (240) to accommodate such differences while occluding ports in head (202) and keeping channels separated from each other so that each channel can be flushed independently of the other channels. Otherwise, a blockage in one channel might merely redirect flow to a connected unblocked channel.

**[0027]** A leakage port (254) on end section (224) leads into an interior portion (256) of endoscope (200) and is used to check for the physical integrity thereof, namely to ensure that no leakage has formed between any of the channels and the interior (256) or from the exterior to the interior (256).

## II. Exemplary Medical Device Reprocessing Method with Single-Use Disinfectant

**[0028]** In an exemplary use of reprocessing system (2), an operator may start by actuating a foot pedal (not shown) to open basin lid (16a). Each lid (16a, 16b) may have its own foot pedal. In some versions, once pressure is removed from the foot pedal, the motion of lid (16a, 16b) stops. With lid (16a) open, the operator inserts shaft (208) of endoscope (200) into helical circulation tube (64). End section (224) and head section (202) of endoscope (200) are situated within basin (14a), with feed hose (222) coiled within basin (14a) with as wide a diameter as possible. Next, flush lines (30) are attached to respective endoscope openings (226, 228, 228a, 230, 232). Air line (112) is also connected to connector (254). In some versions, flush lines (30) are color coded, and guide located on station (10) provides a reference for the color-coded connections.

**[0029]** Depending on the customer-selectable configuration, control system (20) may prompt the operator to enter a user code, patient ID, endoscope code, and/or specialist code. This information may be entered manually (e.g., through touch screen (22)), automatically (e.g., by using an attached barcode wand), or in any other suitable fashion. With the information entered (if required), the operator may then close lid (16a). In some versions, closing lid (16a) requires the operator to press a hardware button and a touch-screen (22) button simultaneously to provide a fail-safe mechanism for preventing the operator's hands from being caught or pinched by the closing basin lid (16a). If either the hardware button or software button is released while lid (16a) is in the process of closing, the motion of lid (16a) stops.

**[0030]** Once lid (16a) is closed, the operator presses a button on touch-screen (22) to begin the washing/disinfection process. At the start of the washing/disinfection process, air pump (38) is activated and pressure within the body of endoscope (200) is monitored. When pressure reaches a predetermined level (e.g., 250 mbar), pump (38) is deactivated, and the pressure is allowed to stabilize for a certain stabilization period (e.g., 6 seconds). If pressure has not reached a certain pressure (e.g., 250 mbar) in a certain time period (e.g., 45 seconds), the program is stopped and the operator is notified of a leak. If pressure drops below a threshold (e.g., less than 100 mbar) during the stabilization period, the program is stopped and the operator is notified of the condition. Once the pressure has stabilized, the pressure drop is monitored over the course of a certain duration (e.g., 60 seconds). If the pressure drop is faster than a predetermined rate (e.g., more than 10 mbar within 60 seconds), the program is stopped and the operator is notified of the condition. If the pressure drop is slower than a predetermined rate (e.g., less than 10 mbar in 60 seconds), reprocessing system (2) continues with the next step. A slight positive pressure is held within the body of endoscope (200) during the rest of the process to prevent fluids from leaking in.

**[0031]** A second leak test checks the adequacy of connection to the various ports (226, 228, 228a, 230, 232) and the proper placement of channel separator (240). A quantity of water is admitted to basin (14a) so as to submerge the distal end of endoscope (200) in helical tube (64). Valve (S1) is closed and valve (S7) opened; and pumps (32) are run in reverse to draw a vacuum and to ultimately draw liquid into endoscope channels (210, 212). Pressure sensors (42) are monitored to make sure that the pressure in any one channel (210, 212) does not drop and/or raise by more than a predetermined amount in a given time frame. If it does, it likely indicates that one of the connections was not made correctly and air is leaking into channel (210, 212). In any event, in the presence of an unacceptable pressure drop, control system (20) will cancel the cycle and indicate a likely faulty connection, preferably with an indication of which channel (210, 212) failed.

**[0032]** In the event that the leak tests are passed, reprocessing system (2) continues with a pre-rinse cycle. The purpose of this step is to flush water through channels (210, 212, 213, 214, 217, 218) to remove waste material prior to washing and disinfecting endoscope (200). To initiate the pre-rinse cycle, basin (14a) is filled with filtered water and the water level is detected by pressure sensor (59) below basin (14a). The water is pumped via pumps (32) through the interior of channels (210, 212, 213, 214, 217, 218), directly to drain (74). This water is not recirculated around the exterior surfaces of endoscope 200 during this stage. As the water is being pumped through channels (210, 212, 213, 214, 217, 218), drain pump (72) is activated to ensure that basin (14a) is also emptied. Drain pump (72) will be turned off when drain switch (76) detects that the drain process is complete. During the draining process, sterile air is blown via air pump (38) through all endoscope channels (210, 212, 213, 214, 217, 218) simultaneously, to minimize potential carryover.

**[0033]** Once the pre-rinse cycle is complete, reprocessing system (2) continues with a wash cycle. To begin the wash cycle, basin (14a) is filled with warm water (e.g., approximately 35°C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by pressure sensor (59). Reprocessing system (2) then adds enzymatic detergent to the water circulating in reprocessing system (2) by means of peristaltic metering pump

(88). The volume is controlled by controlling the delivery time, pump speed, and inner diameter of the tubing of pump (88). Detergent solution (86) is actively pumped throughout the internal endoscope channels (210, 212, 213, 214, 217, 218) and over the outer surface of endoscope (200) for a predetermined time period (e.g., from one to five minutes, or more particularly about three minutes), by channel pumps (32) and external circulation pump (70). Inline heater (80)

keeps the temperature at a predetermined temperature (e.g., approximately about 35° C).

**[0034]** After detergent solution (86) has been circulating for a certain period of time (e.g., a couple of minutes), the flow rate through channels (210, 212, 213, 214, 217, 218) is measured. If the flow rate through any channel (210, 212, 213, 214, 217, 218) is less than a predetermined rate for that channel (210, 212, 213, 214, 217, 218), the channel (210, 212, 213, 214, 217, 218) is identified as blocked, the program is stopped, and the operator is notified of the condition. Peristaltic pumps (32) are run at their predetermined flow rates and cycle off in the presence of unacceptably high pressure readings at the associated pressure sensor (42). If a channel (210, 212, 213, 214, 217, 218) is blocked, the predetermined flow rate will trigger pressure sensor (42), indicating the inability to adequately pass this flow rate. As pumps (32) are peristaltic in the present example, their operating flow rate combined with the percentage of time they are cycled off due to pressure will provide the actual flow rate. The flow rate can also be estimated based upon the decay of the pressure from the time pump (32) cycles off.

**[0035]** At the end of the wash cycle, drain pump (72) is activated to remove detergent solution (86) from basin (14a) and channels (210, 212, 213, 214, 217, 218). Drain pump (72) turns off when drain level sensor (76) indicates that drainage is complete. During the drain process, sterile air is blown through all channels (210, 212, 213, 214, 217, 218) of endoscope (200) simultaneously to minimize potential carryover.

**[0036]** After the wash cycle is complete, reprocessing system (2) begins a rinse cycle. To initiate this rinse cycle, basin (14a) is again filled with warm water (e.g., at approximately 35° C.). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by pressure sensor (59). The rinse water is circulated within channels (210, 212, 213, 214, 217, 218) of endoscope (200) via channel pumps (32); and over the exterior of endoscope (200) via circulation pump (70) and sprinkler arm (60) for a certain period of time (e.g., one minute). As rinse water is pumped through channels (210, 212, 213, 214, 217, 218), the flow rate through channels (210, 212, 213, 214, 217, 218) is measured and if it falls below the predetermined rate for any given channel (210, 212, 213, 214, 217, 218), that channel (210, 212, 213, 214, 217, 218) is identified as blocked, the program is stopped, and the operator is notified of the condition.

**[0037]** At the end of the rinse cycle, drain pump (72) is activated to remove the rinse water from basin (14a) and channels (210, 212, 213, 214, 217, 218). Drain pump (72) turns off when drain level sensor (76) indicates that drainage is complete. During the drain process, sterile air is blown through all channels (210, 212, 213, 214, 217, 218) of endoscope (200) simultaneously to minimize potential carryover. In some versions, the above-described rinsing and draining cycles are repeated at least once again, to ensure maximum rinsing of detergent solution (86) from the surfaces of endoscope (200) and basin (14a).

**[0038]** After reprocessing system (2) has completed the desired number of rinsing and drying cycles, reprocessing system (2) proceeds to a disinfection cycle. To initiate the disinfection cycle, basin (14a) is filled with very warm water (e.g., at approximately 53° C.). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by pressure sensor (59). During the filling process, channel pumps (32) are off in order to ensure that the disinfectant solution (92) in basin (14a) is at the in-use concentration prior to circulating through channels (210, 212, 213, 214, 217, 218) of endoscope (200).

**[0039]** Next, a measured volume of disinfectant solution (92) is drawn from disinfectant metering pre-chamber (96) and delivered into the water in basin (14a) via metering pump (100). The volume of disinfectant solution (92) is controlled by the positioning of fill level switch (98) relative to the bottom of metering pre-chamber (96). Metering pre-chamber (96) is filled until fill level switch (98) detects liquid. Disinfectant solution (92) is drawn from metering pre-chamber (96) until the level of disinfectant solution (92) in metering pre-chamber (96) is just below the tip of metering pre-chamber (96). After the necessary volume is dispensed, metering pre-chamber (96) is refilled from the bottle of disinfectant solution (92). Disinfectant solution (92) is not added until basin (14a) is filled, so that in case of a water supply problem, concentrated disinfectant is not left on endoscope (200) with no water to rinse it. While disinfectant solution (92) is being added, channel pumps (32) are off in order to ensure that disinfectant solution (92) in basin (14a) is at the desired in-use concentration prior to circulating through channels (210, 212, 213, 214, 217, 218) of endoscope (200).

**[0040]** The in-use disinfectant solution (92) is actively pumped throughout internal channels (210, 212, 213, 214, 217, 218) by pumps (32) and over the outer surface of endoscope (200) by circulation pump (70). This may be done for any suitable duration (e.g., at least 5 minutes). The temperature of the disinfectant solution (92) may be controlled by in-line heater (80) to stay at a consistent temperature (e.g., about 52.5° C). During the disinfection process, flow through each channel (210, 212, 213, 214, 217, 218) of endoscope (200) is verified by timing the delivery of a measured quantity of solution through channel (210, 212, 213, 214, 217, 218). Valve (S1) is closed, and valve (S7) opened, and in turn each channel pump (32) delivers a predetermined volume to its associated channel (210, 212, 213, 214, 217, 218) from metering tube (136). This volume and the time it takes to deliver the volume, provides a very accurate flow rate through

the channel (210, 212, 213, 214, 217, 218). Anomalies in the flow rate from what is expected for a channel (210, 212, 213, 214, 217, 218) of that diameter and length are flagged by control system (20) and the process stopped. As in-use disinfectant solution (92) is pumped through channels (210, 212, 213, 214, 217, 218), the flow rate through channels (210, 212, 213, 214, 217, 218) is also measured as described above.

**[0041]** At the end of the disinfection cycle, drain pump (72) is activated to remove disinfectant solution (92) solution from basin (14a) and channels (210, 212, 213, 214, 217, 218). During the draining process, sterile air is blown through all channels (210, 212, 213, 214, 217, 218) of endoscope (200) simultaneously to minimize potential carryover.

**[0042]** After disinfectant solution (92) has been drained from basin (14a), reprocessing system (2) begins a final rinse cycle. To initiate this cycle, basin (14a) is filled with sterile warm water (e.g., at approximately 45° C) that has been passed through a filter (e.g., a 0.2µm filter). The rinse water is circulated within channels (210, 212, 213, 214, 217, 218) by pumps (32); and over the exterior of endoscope (200) via circulation pump (70) and sprinkler arm (60) for a suitable duration (e.g., 1 minute). As rinse water is pumped through channels (210, 212, 213, 214, 217, 218), the flow rate through channels (210, 212, 213, 214, 217, 218) is measured as described above. Drain pump (72) is activated to remove the rinse water from basin (14a) and channels (210, 212, 213, 214, 217, 218). During the draining process, sterile air is blown through all channels (210, 212, 213, 214, 217, 218) of endoscope (200) simultaneously to minimize potential carryover. In some versions, the above-described rinsing and draining cycles are repeated at least two more times, to ensure maximum rinsing of disinfectant solution (92) residuals from the surfaces of endoscope (200) and basin (14a).

**[0043]** After the final rinse cycle is complete, reprocessing system (2) begins a final leak test. In particular, reprocessing system (2) pressurizes the body of endoscope (200) and measures the leak rate as described above. If the final leak test is successful, reprocessing system (2) indicates the successful completion of the cycles via touch-screen (22). From the time of program completion to the time at which lid (16a) is opened, pressure within the body of endoscope (200) is normalized to atmospheric pressure by opening vent valve (S5) at a predetermined rate (e.g., valve (S5) opened for 10 seconds every minute).

**[0044]** Depending on customer-selected configuration, reprocessing system (2) may prevent lid (16a) from being opened until a valid user identification code is entered. Information about the completed program, including the user ID, endoscope ID, specialist ID, and patient ID are stored along with the sensor data obtained throughout the program. If a printer is connected to reprocessing system (2), and if requested by the operator, a record of the disinfection program will be printed. Once a valid user identification code has been entered, lid (16a) may be opened (e.g., using the foot pedal as described above). Endoscope (200) is then disconnected from flush lines (30) and removed from basin (14a). Lid (16a) can then be closed using both the hardware and software buttons as described above.

### III. Exemplary Medical Device Reprocessing with Reusable Disinfectant

**[0045]** In some instances, it may be desirable to collect and reuse disinfectant one or more times rather than drain and dispose of the disinfectant after a single use. For example, reusing disinfectant uses less total disinfectant over the useful life of reprocessing system (2) and may thus decrease the overall cost of operation. In addition, concentrated disinfectant, such as the disinfectant provided from disinfectant storage (92), may have a damaging effect on one or more portions of reprocessing system (2) until mixed with water as a disinfectant solution in the desired concentrations. Storing and reusing the disinfectant solution thus reduces the presence of concentrated disinfectant and may thus increase the useful life of reprocessing system (2).

**[0046]** FIG. 4 shows an exemplary reprocessing system (310) that has a disinfectant storage reservoir (360) from which to pump the disinfectant to basin (14a) and collect the disinfectant after completion of the disinfection cycle. Alternative versions of reprocessing system (410, 510, 610) discussed herein also include exemplary disinfection storage reservoir (360). It will be appreciated that various aspects of reusing disinfectant may be used with respect to any of reprocessing systems (2, 310, 410, 510, 610) and in any combination as described herein.

**[0047]** As shown in FIG. 4, reprocessing system (310), with second exemplary reprocessing system (310) includes a primary pump (312) that receives the fluid, such as the water and/or disinfectant, and pumps the fluid toward the collection of valves (336, 338, 340, 342, 344) as discussed above with respect to various cycles. More particularly, disinfection valve (340) is configured to transition between a circulation state and a collection state during the disinfection cycle. With disinfection valve (340) in the circulation state, the collection of valves (336, 338, 340, 342, 344) is configured to return disinfectant toward flush lines (30) and nozzle assembly (322) for continued circulation during reprocessing. At the conclusion of the disinfection cycle, disinfection valve (340) transitions from the circulation state to the collection state and, in conjunction with the remaining collection of valves (336, 338, 342, 344), directs the disinfectant into disinfectant storage reservoir (360) for reuse in future disinfection cycles. As used herein, the term "disinfectant" refers to concentrated disinfectant or any solution including disinfectant at any concentration. The term "disinfectant" is thus not intended to unnecessarily limit the invention to a particular concentration or solution of disinfectant.

**[0048]** Reprocessing system (310) further includes disinfectant pump (94) in fluid communication between disinfectant storage reservoir (360) and basin (14a). Disinfectant pump (94) thus pumps the disinfectant directly into basin (14a).



Check valve (330) is also fluidly connected between basin (14a) and disinfectant pump (94) and is configured to inhibit fluid within basin (14a) from flowing backward toward pump (94). In some versions, disinfectant storage reservoir (360) is in the form of a break tank such that primary pump (312) and disinfectant pump (94) are configured to individually and/or simultaneously interact with disinfectant storage reservoir (360). However, it will be appreciated that alternative couplings and other features may be used to fluidly couple any form of disinfectant storage reservoir (360) within reprocessing system (310) for collecting and reusing disinfectant. The invention is thus not intended to be limited to the particular disinfectant storage reservoir (360).

**[0049]** Reprocessing system (310) of this example may be readily incorporated into stations (10, 12) (see FIG. 1) with basins (14a, 14b). Basin (14a) shown in FIG. 4 thus receives water from water source (50) and discharges all water therefrom via drain (74), as discussed above. Exemplary basin (14a) includes a plurality of flush lines (30) extending therein and a nozzle assembly (322) having a plurality of nozzles (324). Each flush line (30) and nozzle (324) is configured to direct the water and/or any additive solution, which may be generally referred to as the fluid, toward endoscope (200) (see FIG. 3) within basin (14a) for reprocessing. As discussed above, flush lines (30) are configured to discharge the fluid into respective channels (210, 212, 217, 218) (see FIG. 3), at respective predetermined conduit flow rates particularly configured for each respective channel (210, 212, 217, 218) (see FIG. 3). To this end, primary pump (312) pumps a predetermined supply flow rate of the fluid collectively to flush lines (30) via a common manifold (326) that is fluidly coupled therebetween.

**[0050]** A plurality of flush valves (314, 316, 318, 320) are positioned respectively in each flush line (30) and are collectively configured to balance fluid flow from primary pump (312) such that each flush line (30) discharges fluid therefrom at respective predetermined conduit flow rates. In some versions, flush lines (30) deliver four different respective predetermined conduit flow rates of fluid to channels (210, 212, 217, 218) (see FIG. 3). In some other versions, one or more of the respective predetermined conduit flow rates are approximately equivalent to accommodate an alternative medical device. In any case, any number of flush lines (30) configured to deliver fluid at any predetermined conduit flow rates may be used to accommodate one or more types of medical devices.

**[0051]** Water source (50) delivers the water to a three-way introduction valve (328), which directs the water through filter (54), check valve (330), and two-way valve (332) into basin (14a). As in reprocessing system (2) (see FIG. 2), the water may be collected to a desirable amount as detected by level sensors (59a, 59b, 76). The water drains from basin (14a) and may pass through heater (80) and two-way valve (334) to reach primary pump (312) for distribution toward flush lines (30) and nozzle assembly (322). More particularly a collection of two-way valves (336, 338, 340, 342, 344) are fluidly connected downstream of primary pump (312) to either allow or inhibit fluid flow therethrough for various cycles as discussed herein. For example, flush valve (336) and nozzle valve (338) are configured to control flow respectively toward flush lines (30) and nozzle assembly (322).

**[0052]** In addition, disinfectant valve (340), drain valve (342), and return valve (344) are respectively configured to provide disinfection of endoscope (200), drainage from reprocessing system (310), and self-disinfection of reprocessing system (310). Disinfection and self-disinfection will be discussed below in additional detail. In the present example, disinfection valve (340), drain valve (342), and return valve (344) are presumed fully closed so as to direct the entirety of the predetermined supply flow of the fluid through the opened flush and nozzle valves (336, 338). However, the collection of valves (336, 338, 340, 342, 344) may be fully opened, partially opened, and/or fully closed so as to direct the fluid in any one of a plurality of desirable ratios to complete the cycles of reprocessing. The invention is thus not intended to be limited specifically to the combination of open and/or closed valves as described herein.

**[0053]** Downstream of flush valve (336), additive storages, such as detergent and alcohol storage (86, 134), and detergent metering pump (88), an alcohol metering pump (346), and a gas pump (38) fluidly connect to be received with or in place of water flowing toward flush lines (30). A series of optional two-way valves (348) may be fluidly connected downstream of pumps (88, 346, 38) for additional flow control of various additives. In any case, the fluid, such as water, is received within manifold (326) at the predetermined supply flow rate. As shown in exemplary reprocessing system (310) of FIG. 4, each of the four flush lines (30) fluidly connects to manifold (326) and extends into basin (14a) for connection with channels (210, 212, 217, 218) (see FIG. 3) of endoscope (200). More particularly, each flush line (30) includes a coupling port (350) within basin (14a) that is configured to fluidly seal against endoscope (200) for fluidly coupling channels (210, 212, 217, 218) (see FIG. 3) with respective flush lines (30).

**[0054]** As briefly discussed above, each flush line (30) includes its respective flush valve (314, 316, 318, 320) configured to balance fluid flows along flush lines (30) according to the predetermined conduit flow rates. In some versions, flush valves (314, 316, 318, 320) are in the form of orifice valves that are sized relative to each to each other to create predetermined restriction on the fluid entering manifold (326) according to the predetermined supply flow rate. As the pressure within the manifold (326) distributes equally through flush lines (30), predetermined conduit flow rates of fluid flow through each respective flush valve (314, 316, 318, 320) and discharge from coupling ports (350). Alternatively, flush valves (314, 316, 318, 320) may each comprise a variable valve configured to provide a discrete, predetermined flow rate so that the operator may adjust various flow rates to accommodate differing medical devices in reprocessing system (310).

**[0055]** Furthermore, nozzle valve (338) also receives the fluid, such as water, from primary pump (312) and directs the fluid toward nozzle assembly (322). Each nozzle (324) is generally identical in the present example and configured to discharge fluid onto the exterior of endoscope (200) (see FIG. 3) within basin (14a) at approximately equivalent predetermined nozzle flow rates. To this end, nozzle valve (338) is configured to further balance the predetermined supply flow rate of fluid with flush valves (314, 316, 318, 320) such that each nozzle (324) and fluid line (30) discharges fluid therefrom according to its predetermined conduit flow rate and predetermined nozzle flow rate, respectively. Similar to flush valves (314, 316, 318, 320), nozzle valve (338) may also be a variable valve configured to set to a discrete, predetermined flow rate so that the operator may adjust various flow rates to accommodate differing medical devices in reprocessing system (310). Alternatively, nozzle valve (338) in an open position may provide negligible resistance such that the various predetermined flow rates are balanced simply by restriction in each respective nozzle (324).

**[0056]** In use, reprocessing system (310) receives water from water supply (50) into basin (14a). Alternatively, basin (14a) may receive one of the additives alone or in combination with the water. In any case, the fluid collected within basin (14a) is received within primary pump (312) and pumped therefrom at the predetermined supply flow rate. The collection of valves (338, 340, 342, 344) are generally configured to direct the fluid at the predetermined supply flow rate toward manifold (326) and nozzle assembly (322). The fluid flowing toward manifold (326) may also receive one of the additives, such as detergent, as discussed above in additional detail.

**[0057]** A predetermined portion of the fluid flows into manifold (326), while a remaining predetermined portion of the fluid flows through nozzle valve (338). Flush valves (336) and nozzle valve (338) generate predetermined restriction in each respective flush line (30) in order to direct fluid flow along each flush line (30) with at least two different respective predetermined conduit flow rates. Such predetermined restriction and restriction results in flush valves (336) and nozzle valve (338) apportioning the fluid flow therethrough according to the various predetermined flow rates. For example, flush valves (336) and nozzle valve (338) may be configured to direct fluid along four flush lines (30) with four different respective predetermined conduit flow rates. Once balanced accordingly, the fluid discharges from each coupling port (350) and into respective channels (210, 212, 217, 218) (see FIG. 3) with the predetermined conduit flow rates for reprocessing endoscope (200) (see FIG. 3). It will be appreciated that generating such predetermined flow rates via valves (336, 338) may be used in any cycle of reprocessing described herein and is not intended to limit the invention to any specific reprocessing cycle.

**[0058]** Reprocessing system (310) of the present example includes only one primary pump (312) supplying the predetermined supply flow rate of fluid to each flush line (30) and nozzle (324). However, it will be appreciated that any number of pumps may be used in combination, such as in series or parallel, to direct fluid as discussed above. It will therefore be appreciated that the invention is not intended to unnecessarily be limited to only one primary pump (312). By way of further example only, reprocessing system (310) may be configured and operable in accordance with at least some of the teachings of U.S. Patent App. No. 15/157,800, entitled "Apparatus and Method for Reprocessing a Medical Device," filed on May 18, 2016, the disclosure of which is incorporated by reference herein.

**[0059]** FIG. 5 shows another exemplary reprocessing system (310'), which has another exemplary disinfectant storage reservoir (360') fluidly connected between disinfectant valve (340) and pump (94). Disinfectant storage reservoir (360') is generally similar to disinfectant storage reservoir (360) (see FIG. 4), but also includes additional features for further preparing and maintaining the disinfectant for reprocessing. Specifically, disinfectant storage reservoir (360') includes a disinfectant heater (361') that is configured to heat the disinfectant for reprocessing. In some versions, disinfectant heater (361') is configured to pre-heat the disinfectant in anticipation of use in order to more quickly heat the fluid circulating through reprocessing system (310') for reasons discussed below in additional detail. Alternatively or in addition, disinfectant heater (361') may heat the disinfectant while flowing from disinfectant storage reservoir (360') toward pump (94) for use. In either case, disinfectant heater (361') may be configured to heat the fluid in conjunction with heater (80) for collectively heating the fluid as it flows through reprocessing system (310').

**[0060]** Disinfectant storage reservoir (360') further includes a maximum level sensor (362'), a minimum level sensor (363'), and a temperature sensor (364') for monitoring the disinfectant flowing through and/or contained within disinfectant storage reservoir (360'). Maximum and minimum level sensors (362', 363') are configured to approximate the amount of disinfectant contained within disinfectant storage reservoir (360') and communicate with another system, such as control system (20) (see FIG. 1). For example, maximum and minimum level sensors (362', 363') and control system (20) (see FIG. 1) collectively monitor the amount of disinfectant to be above the maximum level, below the minimum level, or between the maximum and minimum levels, which is generally desired for operation. Temperature sensor (364') also communicates with another system, such as control system (20) (see FIG. 1), to monitor the temperature of the disinfectant.

**[0061]** In order to further monitor the disinfectant, reprocessing system (310') also includes a disinfectant concentration measuring subsystem (365') that is configured to receive the disinfectant from at least one location within reprocessing system (310') for sampling and testing. To this end, disinfectant concentration measuring subsystem (365') of the present example receives the disinfectant samples from filter (54) and from at least one of flush lines (30). Disinfectant concentration measuring subsystem (365') is configured to test samples of disinfectant received from filter (54) and flush line

(30) for a concentration of disinfectant present within the fluid flowing therethrough. In the event that the measured concentration of disinfectant is not within a predetermined range of concentration or is below a predetermined minimum concentration, disinfectant concentration measuring subsystem (365') notifies the operator accordingly. Such measurement and notification may be further aided by communication with control system (20) (see FIG. 1) discussed above in greater detail.

**[0062]** Upon completion of sampling and testing, the disinfectant drains to drain sump (130) such that disinfectant concentration measuring subsystem (365') is available for further use. In parallel, filter (54) also drains directly to drain sump (130) in the event that fluid is not directed toward disinfectant concentration measuring subsystem (365'). It will be appreciated that various devices and method for measuring disinfectant concentration and notifying the operator may be used as described herein and, as such, the invention is not intended to be unnecessarily limited to any particular disinfectant concentration measuring subsystem. By way of further example only, disinfectant concentration measuring subsystem (365') may be configured and operable in accordance with at least some of the teachings of U.S. Pat. App. No. 15/157,952, entitled "Apparatus and Method to Measure Concentration of Disinfectant in Medical Device Reprocessing System," filed on May 18, 2016, the disclosure of which is incorporated by reference herein.

**[0063]** Additional monitoring is provided in reprocessing system (310') by a basin temperature sensor (366'), a drain sump overflow sensor (367'), and a plurality of flow sensors (368'). Basin temperature sensor (366') is generally configured to measure the temperature of fluid therein, while drain sump overflow sensor (367') is configured to measure an excess of fluid collected within drain sump (130) for alerting the operator. Each flow sensor (368') is configured to measure the volumetric flow rate of fluid flowing therethrough for monitoring the overall circulation of fluid through reprocessing system (310'). Each of temperature sensor (366'), drain sump overflow sensor (367'), and flow sensors (368') may communicate with control system (20) (see FIG. 1) for collective operation with any one or more of the sensors discussed herein for using reprocessing system (310). However, it will be appreciated that alternative devices and methods of monitoring reprocessing system (310') may be used and that the invention described herein is not intended to be unnecessarily limited to reprocessing system (310').

#### IV. Exemplary Medical Device Reprocessing Apparatus and Method for Recurring Flow Cycles

**[0064]** In some instances, it may be desirable to increase the bioburden reduction within an internal channel of an endoscope by directing a flow of various solutions, liquids, and/or pressurized air through the endoscope. Although depositing detergents and/or disinfectants within the internal channel of an endoscope may lower the bioburden level of the channels, decreasing the bioburden level in internal channels of endoscopes to a desired level may be particularly difficult due to the small diameters and sometimes irregular profiles of the internal channels. In some cases, simply maintaining a disinfectant or detergent within the internal channels of an endoscope for a specified duration may significantly increase the time required to achieve the desired level of bioburden reduction efficacy. In some instances, an endoscope (200) may include an elevator channel with a cable or wire positioned therein, such as in a duodenoscope. With the presence of a cable or wire contained within the elevator channel, an additional restriction is created as the volume of disinfectant that can flow through the elevator channel is limited. Where the cable is in the form of a twisted cable, numerous gaps and crevices are present that are capable of housing various bioburdens and other particles.

**[0065]** Internal channels (210, 212, 213, 214, 217, 218) of endoscopes (200), and elevator channels of duodenoscopes, may be formed of a material that is more chemical-resistant than the outer surfaces of endoscopes (200). As merely an illustrative example, internal channels (210, 212, 213, 214, 217, 218) may be formed of Teflon or metals that have a higher tolerance to chemical or heat exposure. Accordingly, internal channels (210, 212, 213, 214, 217, 218) are capable of being exposed to a higher concentration of disinfectant or detergent and/or a higher temperature. Additionally, due to the narrow configuration, and sometimes irregular profile, of internal channels (210, 212, 213, 214, 217, 218), utilizing a higher level of concentration may be desirable to effectively achieve bioburden reduction within internal channels (210, 212, 213, 214, 217, 218) due to the greater difficulty in disinfecting internal channels (210, 212, 213, 214, 217, 218) than the outer surface of endoscope (200).

**[0066]** Reprocessing apparatuses that alternate between directing varying treatment solutions through an endoscope (200) may be desirable to increase the bioburden reduction efficacy of the internal channels (210, 212, 213, 214, 217, 218). Providing a recurring cycle where various liquids, detergents, and disinfectants flow through internal channels (210, 212, 213, 214, 217, 218) of endoscopes (200) may be beneficial to lower the bioburden level within the channel (210, 212, 213, 214, 217, 218). As these types of liquids flow reiteratively through internal channels (210, 212, 213, 214, 217, 218), a shear stress is generated on the inner walls of internal channels (210, 212, 213, 214, 217, 218) proportional to the flow rate. The inner walls of internal channels (210, 212, 213, 214, 217, 218) are limited to the extent of shear stress that they can be exposed to before internal channels (210, 212, 213, 214, 217, 218) become damaged. Thus, it may be desirable to direct pressurized air through internal channels (210, 212, 213, 214, 217, 218) to increase the flow rate of the liquid and displace the liquid contained therein. The flow rate of the liquid in the channel (210, 212, 213, 214, 217, 218) significantly increases as more liquid is displaced with air. The amount of flow rate is inversely proportional

to the length of channels (210, 212, 213, 214, 217, 218), as demonstrated in the Hagen-Poiseuille's equation provided below:

$$Q = \frac{dV}{dt} = v\pi R^2 = \frac{\pi R^4}{8n} \left( -\frac{\Delta P}{\Delta x} \right) = \frac{\pi R^4}{8n} \frac{|\Delta P|}{L};$$

where in compatible units (e.g., SI): "Q" is the volumetric flow rate; "V(t)" is the volume of the liquid transferred as a function of time, "t"; "v" is mean fluid velocity along the length of the tube; "x" is the distance in direction of flow; "R" is the internal radius of the tube; " $\Delta P$ " is the pressure difference between the two ends; "n" is the dynamic fluid viscosity; and "L" is the length of the tube.

**[0067]** In this instance, the shear stress of the inner wall is increased and the amount of bioburden removal is enhanced. The amount of shear stress is proportional to the flow rate, as shown by the following formula:

$$\tau = \frac{32\mu}{\pi D^3} Q \dots (3)$$

where " $\mu$ " is the viscosity of water and "Q" is the flow rate.

**[0068]** Repeatedly directing a stream of pressurized air through the internal channels (210, 212, 213, 214, 217, 218), once a detergent or disinfectant solution has passed therethrough, may be further desirable to flush the remaining liquid out of endoscope (200) to ensure any remnants from a prior cycle is substantially removed. By repeatedly filling and purging the internal channels (210, 212, 213, 214, 217, 218) of an endoscope (200), the total time required to remove a certain level of bioburden may be reduced; and in any subsequent cycle introducing a high concentration of disinfectant, that disinfectant is less likely to be diluted by residual fluid in channels (210, 212, 213, 214, 217, 218). The following description provides various examples of a reprocessing system that is configured to deliver a reiterative cycle of various substances and solutions to the internal channels of a medical instrument. A reprocessing system may include a single pump assembly that is configured to deliver the various substances, such as detergent, water, pressurized air, etc. In this instance, the reprocessing system may be configured to selectively open and close a series of valves to individually deliver the various substances through the single pump assembly. Alternatively, as shown below, a reprocessing system may include a separate, dedicated pump to deliver each varying substance to internal channels (210, 212, 213, 214, 217, 218). Although individual pumps are described below, it should be understood that a single pump system or pump assembly may be utilized to implement the reprocessing methods detailed below.

#### A. Medical Device Reprocessing Apparatus and Method Using PreDiluted Disinfectant

**[0069]** In some instances, as previously discussed above, it may be desirable to reutilize formerly used disinfectant from a prior cleaning cycle of the internal channels (210, 212, 213, 214, 217, 218) of an endoscope (200) in a subsequent cycle. A reprocessing method that involves redepositing the disinfectant within the internal channels (210, 212, 213, 214, 217, 218) of an endoscope (200) for future cycles may be beneficial to adequately disinfect the inner components of the endoscope (200) while reducing the need for additional disinfectant for each subsequent cycle. Reutilizing disinfectant for multiple cleaning cycles may thus minimize costs while achieving a sufficient level of biocidal activity. During each instance of delivering previously utilized disinfectant into internal channels (210, 212, 213, 214, 217, 218), the dilution factor of the disinfectant may decrease dramatically. The concentration of the disinfectant in the channel (210, 212, 213, 214, 217, 218) can be estimated using the following formula:  $C_n = C_i - (C_i \times R^n)$ , where " $C_n$ " is the disinfectant concentration in the channel after "n" number of purge and fill cycles; " $C_i$ " is the initial undiluted disinfectant concentration; and "R" is the remaining percentage of fluid in the channel after purging. The table below shows the channel disinfectant concentration at different parameters:

	Remaining %	Remaining %	Remaining %	Remaining %	Remaining %
Number of Purge & Fill	10%	20%	30%	40%	50%
1	90	80	70	60	50
2	99	96	91	84	75
3	99.9	99.2	97.3	93.6	87.5

**[0070]** The following description provides various examples of a reprocessing system and method configured to adequately decontaminate the internal channels (210, 212, 213, 214, 217, 218) of an endoscope (200) through a recurring cleaning cycle. Ultimately, providing a methodical approach to disinfecting the inner components of an endoscope (200) may be beneficial to ensure the proper degree of bioburden reduction is achieved in each instance. It should be understood that the reprocessing method described below may be readily incorporated into any of the various reprocessing systems (2, 310, 310') and to any of the various endoscopes (200) described above. Other suitable ways in which the below-described reprocessing method may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

**[0071]** FIG. 6 shows a block schematic of an exemplary reprocessing system (410) including a disinfectant storage (411), a detergent storage (415), an air supply system (421), and a water supply (425). Except as otherwise described below, reprocessing system (410), disinfectant storage (411), detergent storage (415), air supply system (421), and water reservoir (425) are configured and operable just like reprocessing system (2, 310, 310'), disinfectant storage (92, 360), disinfectant (86), air supply system (36), and water supply (50), respectively, described above. Internal channels (420) of an endoscope (400) are in fluid communication with disinfectant storage (411), detergent storage (415), air supply system (421) and water reservoir (425) via flush lines (444). Reprocessing system (410) is operable to deliver disinfectant solution (92), detergent solution (86), air and water to internal channels (420) of endoscope (400) individually and sequentially. While only one endoscope (400) is shown as being reprocessed in reprocessing system (410), it should be understood that reprocessing system (410) may be capable of reprocessing more than one endoscope (400) simultaneously and/or in a sequence.

**[0072]** Flush lines (444) include a flush valve (446) for each channel (420) operatively connected to reprocessing system (410). Flush valves (446) are positioned downstream of disinfectant storage (411), detergent storage (415), air supply system (421), and water reservoir (425). In the present example, disinfectant storage (411) is in fluid communication with a disinfectant pump (412), a flow sensor (413) and a check valve (414) in sequence, such that disinfectant pump (412) is configured to transfer disinfectant (92) from disinfectant storage (411) to flow sensor (413) and through check valve (414) via flush lines (444). In this instance, disinfectant solution (92) is a high concentrate disinfectant that is capable of providing adequate bioburden reduction within internal channels (420).

**[0073]** Flow sensor (413) is operable to monitor the flow of concentrated disinfectant (92) delivered from disinfectant pump (412) to internal channels (420) of endoscopes (400). Control system (20) of reprocessing system (410) is configured to execute a control algorithm (see FIG. 7) to open flush valve (446), which is in fluid connection with endoscope (400), and retrieve the data monitored by flow sensor (413). Control system (20) is operable to terminate fluid communication between disinfectant pump (412) and endoscope (400) when the data obtained from flow sensor (413) indicates that internal channel (420) has received a sufficient amount of concentrated disinfectant (92) by closing off flush valve (446).

**[0074]** Similarly, detergent storage (415) is in fluid communication with a detergent pump (416), a flow sensor (417) and a check valve (418) in sequence, such that detergent pump (416) is configured to transfer detergent solution (86) to flow sensor (417) and through check valve (418) via flush lines (444). Flow sensor (417) is operable to monitor the elapsed duration as detergent (86) is delivered from detergent pump (416) to internal channels (420) of endoscope (400). Reprocessing system (410) is configured to terminate the fluid communication between detergent pump (416) and flush valve (446) once the elapsed duration as monitored by flow sensor (417) has reached a predetermined time threshold. Alternatively, or in conjunction, reprocessing system (410) is configured to cease operation of detergent pump (416) from pumping detergent (86) to internal channels (420). In each instance, reprocessing system (410) is configured to close flush valve (446) when internal channel (420) has received a sufficient amount of detergent (86) therein, as sensed by flow sensor (417).

**[0075]** Air supply system (421) is in communication with an air pump (422), a filter (423) and a check valve (424). Air pump (422) is configured to push pressurized air from air supply system (421) through filter (423) and check valve (424), thereby delivering a stream of air into and through internal channels (420) of endoscope (400). Filter (423) is operable to filter and remove microbes from the incoming air stream extracted from air supply system (421). In some illustrative examples, filter (423) comprises a HEPA microbe-removing filter. In some versions, reprocessing system (410) may exclude filter (423) in communication with air pump (422) and check valve (424). Water reservoir (425) is in fluid communication with a water pump (426), a flow sensor (427) and a check valve (428). Water pump (426) is configured to pump water from water reservoir (425) to flow sensor (427) and through check valve (428) via flush lines (444). Reprocessing system (410) is operable to measure the quantity of water delivered from water pump (426) to internal channel (420) of endoscope (400), based on data from flow sensor (427). Reprocessing system (410) is further configured to close flush valve (446) upon determining that internal channel (420) has received a sufficient amount of water therein, as sensed by flow sensor (427).

**[0076]** Reprocessing system (410) further includes basin (14a) in fluid communication with internal channels (420) of endoscope (400) via flush lines (444). Basin (14a) is operable to receive any fluids or air released from internal channels (420). Further, basin (14a) is in fluid communication with disinfectant pump (412) via flush line (444) such that disinfectant

pump (412) is operable to draw the released fluids within basin (14a) to disinfectant pump (412). The released fluid is recycled through reprocessing system (410) when disinfectant pump (412) reactivates to pump a subsequent amount of disinfectant (92) through flow sensor (413), check valve (414) and into internal channels (420). For example, with basin (14a) holding previously used disinfectant (92) recently released from internal channels (420), basin (14a) is operable to transfer the previously used disinfectant (92) to disinfectant pump (412) for reuse. In this instance, disinfectant pump (412) is configured to pump the previously used disinfectant (92) into internal channels (420) again. Simultaneously, disinfectant pump (412) is further configured to obtain a new portion of disinfectant (92) from disinfectant storage (411) for mixture and delivery with the previously used disinfectant (92) received from basin (14a).

**[0077]** As seen in FIG. 6, reprocessing system (410) includes a first variable valve (448) in line between disinfectant storage (411) and disinfectant pump (412) and a second variable valve (450) between basin (14a) and disinfectant pump (412). Reprocessing system (410) is operable to selectively open and close variable valves (448, 450) to draw disinfectant (92) from disinfectant storage (411) and separately, or simultaneously, pull fluid from basin (14a), respectively. For instance, with first variable valve (448) in an open state and with second variable valve (450) in a closed state, operation of disinfectant pump (412) pulls disinfectant (92) from disinfectant storage (411). With first variable valve (448) in a closed state and with second variable valve (450) in an open state, disinfectant pump (412) is operable to draw fluids from within basin (14a).

**[0078]** In some versions, reprocessing system (410) is configured to maintain variable valves (448, 450) simultaneously open. In this instance, unlike flush valves (446), variable valves (448, 450) include variable orifices that are configured to be selectively adjusted. Reprocessing system (410) is configured to adjust the size of the orifice of variable valves (448, 450) to thereby selectively control the amount of disinfectant (92) pulled from disinfectant storage (411) and the amount of released fluids drawn from basin (14a) through the operation of disinfectant pump (412). In this instance, reprocessing system (410) is operable to cooperatively manipulate the opening dimensions of variable valves (448, 450) to thereby deliver varied doses and/or concentrations of disinfectant (92) to internal channels (410) during subsequent disinfecting cycles. Although not shown, it should be understood that reprocessing system (410) may include a single pump assembly such that the same pump assembly is configured to deliver detergent (86), water, pressurized air, and detergent (92). In this instance, reprocessing system (410) is configured to selectively open and close a series of flush valves (446) to individually deliver the various substances with the single pump assembly.

**[0079]** FIG. 7 shows a flow diagram illustrating steps of an exemplary reprocessing method (480) that may be used by reprocessing system (410) to perform a predetermined number of fill and purge cycles of internal channels (420) of endoscope (400). At step (482), reprocessing system (410) initiates detergent pump (412) to deliver detergent solution (86) to endoscope (400) via flush lines (444). Reprocessing system (410) is configured to deliver detergent (86) through internal channels (420) at a predetermined flow rate. At step (484), as detergent (86) is transferred from detergent storage (415) to endoscope (400), flow sensor (417) measures an elapsed duration of flow as detergent pump (416) actively pumps detergent (86) toward internal channels (420). Reprocessing system (410) ceases operation of detergent pump (416) when the elapsed flow time equals a predetermined time threshold for detergent delivery. Subsequently, at step (486), reprocessing system (410) initiates water pump (426) to deliver water to endoscope (400) via flush lines (444) and through internal channels (420), to thereby rinse any remaining detergent (86) out from internal channels (420) and into basin (14a). In this instance, flow sensor (427) measures an elapsed duration of flow as water pump (426) actively pumps water toward internal channels (420). Reprocessing system (410) ceases operation of water pump (426) when the elapsed flow time equals a predetermined time threshold for rinsing.

**[0080]** At step (488), reprocessing system (410) initiates air pump (422) to send pressurized air from air supply system (421) through filter (423) and into endoscope (400). The stream of air passes through internal channels (420) thereby purging internal channels (420) of any residual detergent (86) or water contained therein. Air pump (422) continues to flow pressurized air through internal channels (420) until a specified flow duration elapses, signaling for reprocessing system (410) to cease operation of air pump (422). Reprocessing system (410) terminates air pump (422) once the elapsed flow time has reached a predetermined time threshold for air purging. At step (490), with air pump (422) inactive, disinfectant pump (412) beings to pump high concentrate disinfectant (92) to internal channels (420) of endoscope (400) simultaneously.

**[0081]** Reprocessing system (410) monitors the volume of disinfectant (92) transferred from disinfectant storage (411) to endoscope (400) and ceases operation of disinfectant pump (412) when the volume delivered substantially equals a predetermined threshold, as seen at step (492). Reprocessing system (410) closes all flush valves (446) simultaneous with the deactivation of disinfectant pump (412). In this instance, as seen at step (494), reprocessing system (410) evaluates whether internal channels (420) of endoscope (400) have stored the high concentrate disinfectant (92) for a minimum dwell time. As merely an illustrative example, the predetermined dwell time can range between approximately 10 seconds to 30 seconds. Although not shown, it should be understood that in some versions reprocessing system (410) may forego holding the high concentrate disinfectant (92) in the internal channels (420) for the minimum dwell time. Instead, flush valves (446) may remain open after the deactivation of disinfectant pump (412) and reprocessing system (410) may initiate water pump (526) and air pump (422), respectively in sequential order as described above.

**[0082]** At step (496), once reprocessing system (410) has determined that internal channels (420) have maintained disinfectant (92) for the minimum dwell time, flush valves (446) are reopened and air pump (422) is reactivated. In this instance, pressurized air is flowed through internal channels (420) to thereby purge disinfectant (92) from endoscope (400). The flow rate of disinfectant (92) being released from within internal channels (420) into basin (14a) is increased due to the flow of pressurized air, thereby enhancing the bioburden removal. At step (497), with disinfectant (92) released into basin (14a) and contained therein, reprocessing system (410) determines whether the above described fill and purge process has been performed a predetermined "n" number of times. By way of example only, the predetermined "n" number of times may be two times, three times, four times, five times, six times, or more times. Upon the determination by reprocessing system (410) that additional fill and purge cycles remain to be completed, reprocessing system (410) transfers the previously used disinfectant (92) from basin (14a) to disinfectant pump (412) for subsequent use in the next cycle, as seen in step (498).

**[0083]** In this instance, reprocessing system (410) will continue to perform step (490) through step (497) until reprocessing system (410) determines that no additional fill and purge cycles remain to be completed. In other words, reprocessing method (480) will proceed to step (499) when reprocessing system (410) has performed reprocessing method (480) the predetermined "n" number of times. At step (499), reprocessing system (410) ceases continuation of reprocessing method (480).

#### B. Medical Device Reprocessing Apparatus and Method Using Concentrated Disinfectant

**[0084]** As previously mentioned, in some instances an endoscope (200) may include an elevator channel with a cable or wire positioned therein, such as in a duodenoscope. The cable contained within an elevator channel of a duodenoscope may be in the form of a twisted cable having various gaps and crevices capable of housing bioburdens, water, particles, and other substances therebetween. Further, due to the surface tension of the twisted cable or wire, water and other particles may remain in the gaps and crevices even after a disinfectant is delivered into the elevator channel. The remaining water or other substances contained within the elevator channel may tend to dilute any disinfectant subsequently delivered into the elevator channel for disinfection, thereby rendering the process of reducing the bioburden level of the internal channels more difficult. Additionally, the presence of the cable or wire within the elevator channel creates an additional restriction as the cable or wire significantly limits the volume of disinfectant that can flow through the elevator channel.

**[0085]** Ultimately, with an elevator channel having a small diameter and the presence of a cable or wire contained therein, the challenge to reduce the bioburden level in the endoscope (200) significantly increases. Providing a reprocessing system and method similar to reprocessing system (410) and reprocessing method (480) described above, may be desirable to adequately disinfect the internal channels of an endoscope through a recurring cleaning cycle. However, with the enhanced difficulties in reprocessing elevator channels containing a cable or wire contained therein, it may be desirable for the reprocessing system and method to utilize disinfectant concentrate during each cycle. In this instance, previously used disinfectant is not recycled through the reprocessing system to ensure the concentration of the disinfectant is relatively high for each recurring cycle to sufficiently increase the bioburden reduction efficacy in the elevator channel of a duodenoscope.

**[0086]** Providing a methodical approach to disinfecting the inner components of an endoscope may be beneficial to ensure the proper degree of bioburden reduction is achieved in each instance. The following description provides various examples of a reprocessing system and method configured to adequately disinfect the internal channels of an endoscope (200) through a recurring cleaning cycle using concentrated disinfectant for each cycle. It should be understood that the reprocessing method described below may be readily incorporated into any of the various reprocessing systems (2, 310, 310', 410) and to any of the various endoscopes (200) described above. Other suitable ways in which the below-described reprocessing method may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

**[0087]** FIG. 8 shows a block schematic of an exemplary reprocessing system (510) including a disinfectant storage (511), a detergent storage (515), an air supply system (521), and a water supply (525). Except as otherwise described below, reprocessing system (510), disinfectant storage (511), detergent storage (515), air supply system (521), and water reservoir (525) are configured and operable just like reprocessing system (2, 310, 310', 410), disinfectant storage (92, 360, 411), disinfectant storage (86, 415), air supply system (36, 421), and water supply (50, 425), respectively, described above. Internal channels (520) of an endoscope (500) are in fluid communication with disinfectant storage (411), detergent storage (515), air supply system (521) and water reservoir (525) via flush lines (544). Reprocessing system (510) is operable to deliver disinfectant solution (92), detergent solution (86), air and water to internal channels (520) of endoscope (500) individually and sequentially. While only one endoscope (500) is shown as being reprocessed in reprocessing system (510), it should be understood that reprocessing system (510) may be capable of reprocessing more than one endoscope (500) simultaneously and/or in a sequence.

**[0088]** Flush lines (544) include a flush valve (546) for each channel (520) operatively connected to reprocessing system (510). Flush valves (546) are positioned downstream of disinfectant storage (511), detergent storage (515), air

supply system (521), and water reservoir (525). In the present example, disinfectant storage (511) is in fluid communication with a disinfectant pump (512), a flow sensor (513) and a check valve (514) in sequence, such that disinfectant pump (512) is configured to transfer disinfectant (92) from disinfectant storage (511) to flow sensor (513) and through check valve (514) via flush lines (544). In this instance, disinfectant solution (92) is a high concentrate disinfectant or sterilant that is capable of providing adequate bioburden reduction within internal channels (520).

**[0089]** Flow sensor (513) is operable to monitor the flow of concentrated disinfectant (92) delivered from disinfectant pump (512) to internal channels (520) of endoscopes (500). Control system (20) of reprocessing system (510) is configured to execute a control algorithm (see FIG. 9) to open flush valve (546), which is in fluid connection with endoscope (500), and retrieve the data monitored by flow sensor (513). Control system (20) is operable to terminate fluid communication between disinfectant pump (512) and endoscope (500) when the data indicates that internal channels (520) have received a sufficient amount of disinfectant (92) by closing flush valves (546).

**[0090]** Similarly, detergent storage (515) is in fluid communication with a detergent pump (516), a flow sensor (517) and a check valve (518) in sequence, such that detergent pump (516) is configured to transfer detergent solution (86) to flow sensor (517) and through check valve (518) via flush lines (544). Flow sensor (517) is operable to monitor the elapsed duration as detergent (86) is delivered from detergent pump (516) to internal channels (520) of endoscope (500). In other words, reprocessing system (510) is configured to terminate the fluid communication between detergent pump (516) and flush valves (546), by closing flush valves (546), once the elapsed duration monitored by flow sensor (517) has met a predetermined time threshold for delivering detergent (86) to endoscope (500). Alternatively, or in conjunction, reprocessing system (510) is configured to cease operation of detergent pump (516) from pumping detergent (86) to internal channels (520). In each instance, reprocessing system (510) is configured to close flush valves (546) when internal channels (520) have received a sufficient amount of detergent (86) therein, as sensed by flow sensor (517).

**[0091]** Air supply system (521) is in communication with an air pump (522), a filter (523) and a check valve (524). Air pump (522) is configured to push pressurized air from air supply system (521) through filter (523) and check valve (524), thereby delivering a stream of air into and through internal channels (520) of endoscope (500). Filter (523) is operable to filter and remove microbes from the incoming air stream extracted from air supply system (521). In some illustrative examples, filter (523) comprises a HEPA microbe-removing filter. In some versions, reprocessing system (510) may exclude filter (523) in communication with air pump (522) and check valve (524). Water reservoir (525) is in fluid communication with a water pump (526), a flow sensor (527) and a check valve (528). Water pump (526) is configured to pump water from water reservoir (525) to flow sensor (527) and through check valve (528) via flush lines (544).

**[0092]** Reprocessing system (510) is operable to open flush valve (546) and to measure the quantity of water delivered from water pump (526) to internal channels (520) of endoscope (500). Flow sensor (527) is operable to monitor the quantity of water delivered to internal channels (520). In this instance, reprocessing system (510) is configured to close flush valve (546) when internal channels (520) have received a sufficient amount of water. Reprocessing system (510) further includes basin (14a) in fluid communication with internal channels (520) of endoscope (500) via flush lines (544). Basin (14a) is operable to receive any fluids or air released from internal channels (520). As previously mentioned, although not shown, it should be understood that reprocessing system (510) may include a single pump assembly such that the same pump is configured to deliver detergent (86), water, pressurized air, and concentrated detergent (92). In this instance, reprocessing system (510) is configured to selectively open and close a series of flush valves (546) to individually deliver the various substances with the single pump assembly.

**[0093]** FIG. 9 shows a flow diagram illustrating steps of an exemplary reprocessing method (580) that may be used by reprocessing system (510) to perform a predetermined number of fill and purge cycles of internal channels (520) of endoscope (500). At step (582), reprocessing system (510) initiates detergent pump (512) to deliver detergent solution (86) to endoscope (500) via flush lines (544). Reprocessing system (510) is configured to deliver detergent (86) through internal channels (520) at a predetermined flow rate. At step (584), as detergent (86) is transferred from detergent storage (515) to endoscope (500), flow sensor (517) measures an elapsed duration of flow as detergent pump (516) actively pumps detergent (86) toward internal channels (520). Reprocessing system (510) ceases operation of detergent pump (516) when the elapsed flow time equals a predetermined time threshold for detergent delivery. Subsequently, at step (586), reprocessing system (510) initiates water pump (526) to deliver water to endoscope (500) via flush lines (544) and through internal channels (520), to thereby rinse any remaining detergent (86) out from internal channels (520) and into basin (14a). In this instance, flow sensor (527) measures an elapsed duration of flow as water pump (526) pumps water into internal channel (520). Reprocessing system (510) ceases operation of water pump (526) when the elapsed flow time equals a predetermined time threshold for rinsing.

**[0094]** At step (588), reprocessing system (510) initiates air pump (522) to send pressurized air from air supply system (521) through filter (523) and into endoscope (500). The stream of air passes through internal channels (520) thereby purging internal channels (520) of any residual detergent (86) or water contained therein. Air pump (522) continues to flow pressurized air through internal channels (520) until a specified flow duration elapses signaling for reprocessing system (510) to cease operation of air pump (522). Reprocessing system (510) terminates air pump (522) once the elapsed flow time has reached a predetermined time threshold for air purging. At step (590), with air pump (522) inactive,



disinfectant pump (512) beings to pump high concentrate disinfectant (92) to internal channels (520) of endoscope (500) simultaneously. Reprocessing system (510) monitors the volume of disinfectant (92) transferred from disinfectant storage (511) to endoscopes (500) and ceases operation of disinfectant pump (512) when the volume delivered substantially equals a predetermined threshold, as seen at step (592). Reprocessing system (510) closes all flush valves (546) simultaneous with the deactivation of disinfectant pump (512). In this instance, as seen at step (594), reprocessing system (510) evaluates whether internal channels (520) of endoscope (500) has stored the high concentrate disinfectant (92) for a minimum dwell time. As merely an illustrative example, the predetermined dwell time can range between approximately 10 seconds to 30 seconds. Although not shown, it should be understood that in some versions reprocessing system (510) may forego holding the high concentrate disinfectant (92) in the internal channels (520) for the minimum dwell time. Instead, flush valves (546) may remain open after the deactivation of disinfectant pump (512) and reprocessing system (510) may initiate water pump (526) and air pump (522), respectively in sequential order as described above.

**[0095]** At step (596), once reprocessing system (510) has determined that internal channels (520) have maintained disinfectant (92) for the minimum dwell time, flush valves (546) are reopened and air pump (522) is reactivated. In this instance, pressurized air is flowed through internal channels (520) to thereby purge disinfectant (92) from endoscope (500). The flow rate of disinfectant (92) being released from within internal channels (520) into basin (14a) is increased due to the flow of pressurized air, thereby enhancing the bioburden removal. At step (598), with disinfectant (92) released into basin (14a) and contained therein, reprocessing system (510) determines whether the above described fill and purge process has been performed predetermined "n" number of times. Upon the determination by reprocessing system (510) that additional fill and purge cycles remain to be completed, reprocessing system (510) will continue to perform step (590) through step (598) until reprocessing system (510) determines that no additional fill and purge cycles remain to be completed. In other words, reprocessing method (580) will proceed to step (599) when reprocessing system (510) has performed reprocessing method (580) the predetermined "n" number of times. At step (599), reprocessing system (510) ceases continuation of reprocessing method (480).

#### V. Exemplary Combinations

**[0096]** The following examples relate to various non-exhaustive ways in which the teachings herein may be combined or applied. It should be understood that the following examples are not intended to restrict the coverage of any claims that may be presented at any time in this application or in subsequent filings of this application. No disclaimer is intended. The following examples are being provided for nothing more than merely illustrative purposes. It is contemplated that the various teachings herein may be arranged and applied in numerous other ways. It is also contemplated that some variations may omit certain features referred to in the below examples. Therefore, none of the aspects or features referred to below should be deemed critical unless otherwise explicitly indicated as such at a later date by the inventors or by a successor in interest to the inventors. If any claims are presented in this application or in subsequent filings related to this application that include additional features beyond those referred to below, those additional features shall not be presumed to have been added for any reason relating to patentability.

##### Example 1

**[0097]** A method for reprocessing an internal channel of at a medical device, the method comprising: (a) activating a first pump to deliver a detergent to the internal channel for a first predetermined duration; (b) activating a second pump to deliver water to the internal channel to rinse out the detergent for a second predetermined duration; (c) activating a third pump to deliver pressurized air to the internal channel to purge out any remaining water or detergent contained within the internal channel for a third predetermined duration; (d) activating a fourth pump to deliver a predetermined volume of disinfectant to the internal channel; (e) reactivating the third pump to deliver pressurized air to the internal channel to purge out the disinfectant from the internal channel into a chamber; (f) reactivating the fourth pump to deliver additional disinfectant to the internal channel; and (g) reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional disinfectant from the internal channel into the chamber.

##### Example 2

**[0098]** The method of Example 1, further comprising activating the third pump after the first predetermined duration to deliver pressurized air to the internal channel to purge out the detergent contained within the internal channel.

##### Example 3

**[0099]** The method of Example 2, further comprising: (a) reactivating the first pump to deliver additional detergent to the internal channel for a first predetermined duration; and (b) reactivating the third pump to deliver pressurized air to

the internal channel to purge out the additional detergent from the internal channel.

Example 4

5 **[0100]** The method of Example 3, further comprising repeating the acts of reactivating activating the first pump to deliver additional detergent to the internal channel for a first predetermined duration and reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional detergent from the internal channel until a predetermined number of cycles is met.

10 Example 5

**[0101]** The method of any one or more of Examples 1 through 4, further comprising further comprising: (a) reactivating the second pump to deliver additional water to the internal channel for a first predetermined duration; and (b) reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional water from the internal channel.

15 Example 6

**[0102]** The method of Example 5, further comprising repeating the acts of reactivating the second pump to deliver additional water to the internal channel for a first predetermined duration and reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional water from the internal channel until a predetermined number of cycles is met.

Example 7

25 **[0103]** The method of any one or more of Examples 1 through 6, further comprising repeating steps (f) through (g) until a predetermined number of cycles is met.

Example 8

30 **[0104]** The method of any one or more of Examples 1 through 7, wherein the medical device has a plurality of internal channels, the method further comprising repeating steps (a) through (g) for each internal channel of the medical device.

Example 9

35 **[0105]** The method of any one or more of Examples 1 through 8, further comprising determining a concentration of the disinfectant that is output from the chamber.

Example 10

40 **[0106]** The method of any one or more of Examples 1 through 9, further comprising monitoring an elapsed duration for delivering the detergent, further comprising deactivating the first pump when the elapsed duration equals the first predetermined duration.

Example 11

45 **[0107]** The method of any one or more of Examples 1 through 10, further comprising monitoring an elapsed duration for delivering the water in relation to the second predetermined duration, further comprising deactivating the second pump when the elapsed duration equals the second predetermined duration.

50 Example 12

**[0108]** The method of any one or more of Examples 1 through 11, further comprising monitoring a volume of disinfectant delivered, further comprising deactivating the fourth pump when the volume delivered equals a capacity of the internal channel.

55 Example 13

**[0109]** The method of any one or more of Examples 1 through 12, further comprising filtering microbes from the

pressurized air delivered to the internal channel.

Example 14

- 5 **[0110]** The method of any one or more of Examples 1 through 13, further comprising heating the disinfectant delivered to the internal channel by the fourth pump.

Example 15

- 10 **[0111]** The method of any one or more of Examples 1 through 14, further comprising circulating a mixture of the disinfectant and the water in the chamber thereby exposing an outer surface of the medical device to the mixture.

Example 16

- 15 **[0112]** The method of Example 15, further comprising continuing the circulation of the mixture for a predetermined time.

Example 17

- 20 **[0113]** A method for reprocessing an internal channel of at least one medical device, the method comprising: (a) activating a pump assembly to deliver a detergent to the internal channel for a first predetermined duration; (b) reactivating the pump assembly to deliver water to the internal channel to rinse out the detergent for a second predetermined duration; (c) reactivating the pump assembly to deliver pressurized air to the internal channel to purge out any remaining water or detergent contained within the internal channel for a third predetermined duration; (d) reactivating the pump assembly to deliver a predetermined volume of disinfectant to the internal channel; (e) reactivating the pump assembly to deliver  
25 pressurized air to the internal channel to purge out the disinfectant into a chamber; (f) reactivating the pump assembly to deliver a subsequent volume of disinfectant to the internal channel; and (g) reactivating the pump assembly to deliver pressurized air to the internal channel to purge out the subsequent volume of disinfectant into the chamber.

Example 18

- 30 **[0114]** The method of Example 17, further comprising directing the disinfectant in the chamber to the pump assembly.

Example 19

- 35 **[0115]** The method of Example 17, further comprising repeating (f) through (g) until a predetermined number of cycles is met.

Example 20

- 40 **[0116]** A medical device reprocessor comprising: (a) a port that is configured to couple with an internal channel of a medical device; (b) a pump system, wherein the pump system is in fluid communication with a detergent, water, pressurized air, and a disinfectant, wherein the pump system is configured to deliver the detergent to the port, wherein the pump system is further configured to deliver the water to the port, wherein the pump system is further configured to deliver the pressurized air to the port, wherein the pump system is further configured to deliver the disinfectant to the  
45 port; and (c) a control module; wherein the control module is operable to execute a control algorithm to deliver the detergent from the pump system to the port and terminate delivery at a first predetermined time threshold; wherein the control module is operable to execute the control algorithm to deliver the water from the pump system to the port when the first predetermined time threshold is met and terminate delivery at a predetermined volume threshold; wherein the control module is operable to execute the control algorithm to deliver the pressurized air from the pump system to the  
50 port when the predetermined volume threshold is met and terminate delivery at a second predetermined time threshold; wherein the control module is operable to execute the control algorithm to deliver the disinfectant from the pump system to the port when the second predetermined time threshold is met and terminate delivery at the predetermined volume threshold; and wherein the control module is configured to repeat the sequential delivery of the pressurized air and the disinfectant from the pump system to the port for at least a predetermined number of cycles.

55 VI. Miscellaneous

- [0117]** It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is

said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts

with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

**[0118]** Having shown and described various embodiments of the present invention, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, embodiments, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

## Claims

1. A method for reprocessing an internal channel of a medical device, the method comprising:

- (a) activating a first pump to deliver a detergent to the internal channel for a first predetermined duration;
- (b) activating a second pump to deliver water to the internal channel to rinse out the detergent for a second predetermined duration;
- (c) activating a third pump to deliver pressurized air to the internal channel to purge out any remaining water or detergent contained within the internal channel for a third predetermined duration;
- (d) activating a fourth pump to deliver a predetermined volume of disinfectant to the internal channel;
- (e) reactivating the third pump to deliver pressurized air to the internal channel to purge out the disinfectant from the internal channel into a chamber;
- (f) reactivating the fourth pump to deliver additional disinfectant to the internal channel; and
- (g) reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional disinfectant from the internal channel into the chamber.

2. The method of claim 1, further comprising activating the third pump after the first predetermined duration to deliver pressurized air to the internal channel to purge out the detergent contained within the internal channel.

3. The method of claim 2, further comprising:

- (a) reactivating the first pump to deliver additional detergent to the internal channel for a first predetermined duration; and
- (b) reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional detergent from the internal channel.

4. The method of claim 3, further comprising repeating the acts of reactivating activating the first pump to deliver additional detergent to the internal channel for a first predetermined duration and reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional detergent from the internal channel until a predetermined number of cycles is met.

5. The method of any one of claims 1 to 4, further comprising further comprising:

- (a) reactivating the second pump to deliver additional water to the internal channel for a first predetermined duration; and
- (b) reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional water from the internal channel.

6. The method of claim 5, further comprising repeating the acts of reactivating the second pump to deliver additional water to the internal channel for a first predetermined duration and reactivating the third pump to deliver pressurized air to the internal channel to purge out the additional water from the internal channel until a predetermined number of cycles is met.

7. The method of any one of claims 1 to 6, further comprising repeating steps (f) through (g) until a predetermined number of cycles is met.
- 5 8. The method of any one of claims 1 to 7, wherein the medical device has a plurality of internal channels, the method further comprising repeating steps (a) through (g) for each internal channel of the medical device.
9. The method of any one of claims 1 to 8, further comprising determining a concentration of the disinfectant that is output from the chamber.
- 10 10. The method of any one of claims 1 to 9, further comprising monitoring an elapsed duration for delivering the detergent, further comprising deactivating the first pump when the elapsed duration equals the first predetermined duration.
11. The method of any one of claims 1 to 10, further comprising monitoring an elapsed duration for delivering the water in relation to the second predetermined duration, further comprising deactivating the second pump when the elapsed duration equals the second predetermined duration.
- 15 12. The method of any one of claims 1 to 11, further comprising monitoring a volume of disinfectant delivered, further comprising deactivating the fourth pump when the volume delivered equals a capacity of the internal channel.
- 20 13. The method of any one of claims 1 to 12, further comprising filtering microbes from the pressurized air delivered to the internal channel.
- 25 14. The method of any one of claims 1 to 13, further comprising heating the disinfectant delivered to the internal channel by the fourth pump.
15. The method of any one of claims 1 to 14, further comprising circulating a mixture of the disinfectant and the water in the chamber thereby exposing an outer surface of the medical device to the mixture.
- 30 16. The method of claim 15, further comprising continuing the circulation of the mixture for a predetermined time.
17. A method for reprocessing an internal channel of at least one medical device, the method comprising:
  - (a) activating a pump assembly to deliver a detergent to the internal channel for a first predetermined duration;
  - (b) reactivating the pump assembly to deliver water to the internal channel to rinse out the detergent for a second predetermined duration;
  - 35 (c) reactivating the pump assembly to deliver pressurized air to the internal channel to purge out any remaining water or detergent contained within the internal channel for a third predetermined duration;
  - (d) reactivating the pump assembly to deliver a predetermined volume of disinfectant to the internal channel;
  - (e) reactivating the pump assembly to deliver pressurized air to the internal channel to purge out the disinfectant into a chamber;
  - 40 (f) reactivating the pump assembly to deliver a subsequent volume of disinfectant to the internal channel; and
  - (g) reactivating the pump assembly to deliver pressurized air to the internal channel to purge out the subsequent volume of disinfectant into the chamber.
- 45 18. The method of claim 17, further comprising directing the disinfectant in the chamber to the pump assembly.
19. The method of claim 17, further comprising repeating (f) through (g) until a predetermined number of cycles is met.
- 50 20. A medical device reprocessor comprising:
  - (a) a port that is configured to couple with an internal channel of a medical device;
  - (b) a pump system, wherein the pump system is in fluid communication with a detergent, water, pressurized air, and a disinfectant, wherein the pump system is configured to deliver the detergent to the port, wherein the pump system is further configured to deliver the water to the port, wherein the pump system is further configured to deliver the pressurized air to the port, wherein the pump system is further configured to deliver the disinfectant to the port; and
  - 55 (c) a control module;

wherein the control module is operable to execute a control algorithm to deliver the detergent from the pump system to the port and terminate delivery at a first predetermined time threshold;

wherein the control module is operable to execute the control algorithm to deliver the water from the pump system to the port when the first predetermined time threshold is met and terminate delivery at a predetermined volume threshold;

wherein the control module is operable to execute the control algorithm to deliver the pressurized air from the pump system to the port when the predetermined volume threshold is met and terminate delivery at a second predetermined time threshold;

wherein the control module is operable to execute the control algorithm to deliver the disinfectant from the pump system to the port when the second predetermined time threshold is met and terminate delivery at the predetermined volume threshold; and

wherein the control module is configured to repeat the sequential delivery of the pressurized air and the disinfectant from the pump system to the port for at least a predetermined number of cycles.

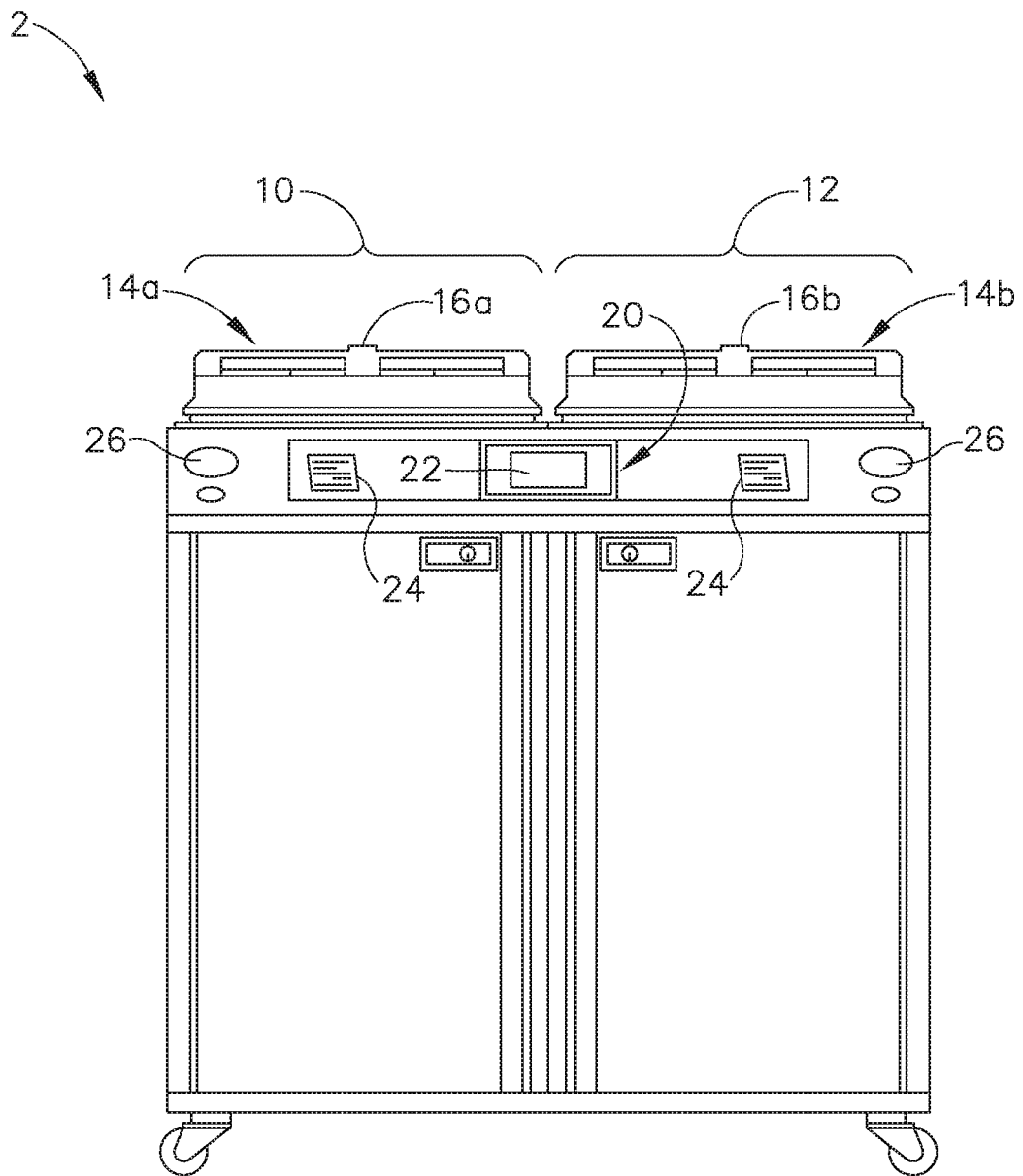
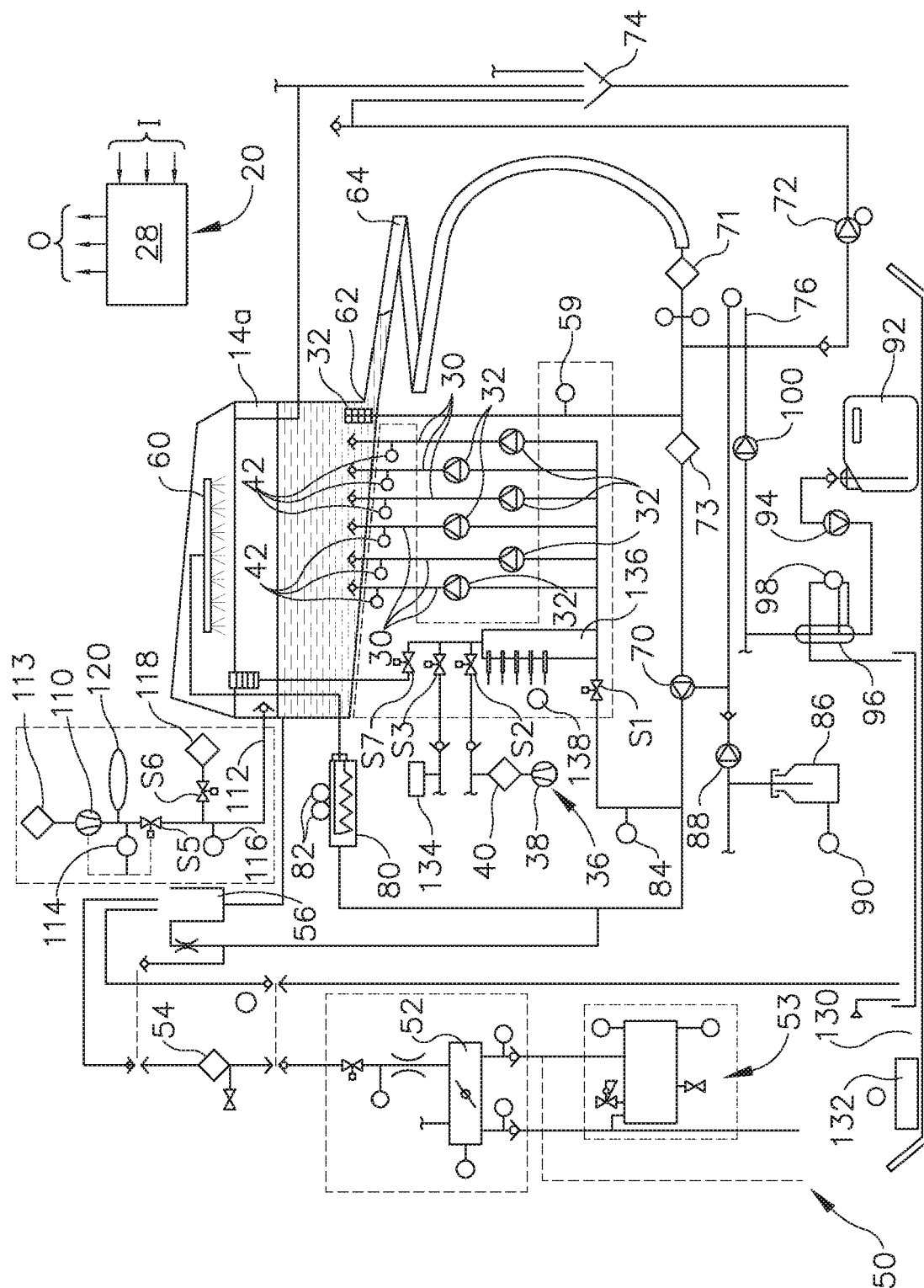
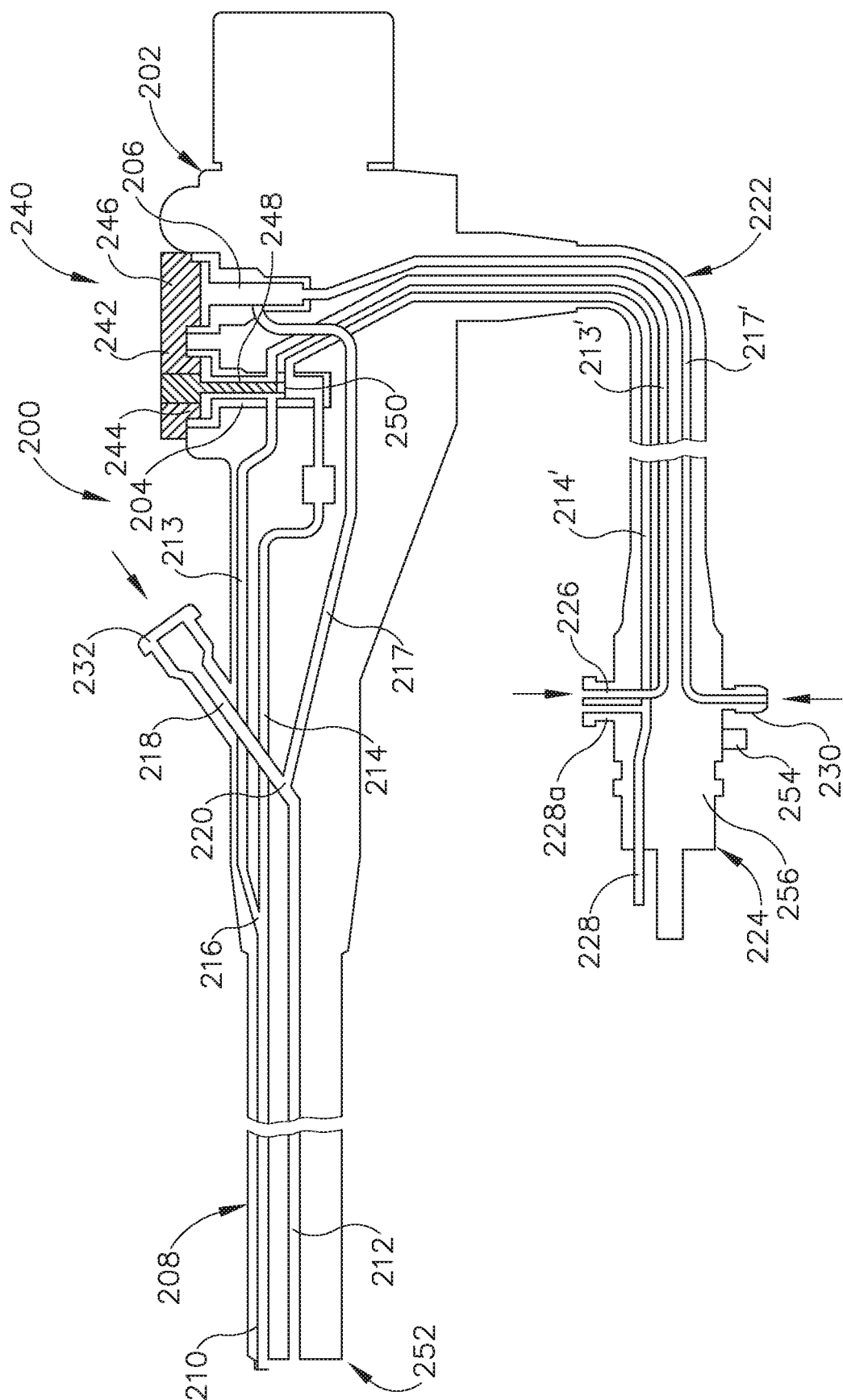


Fig.1

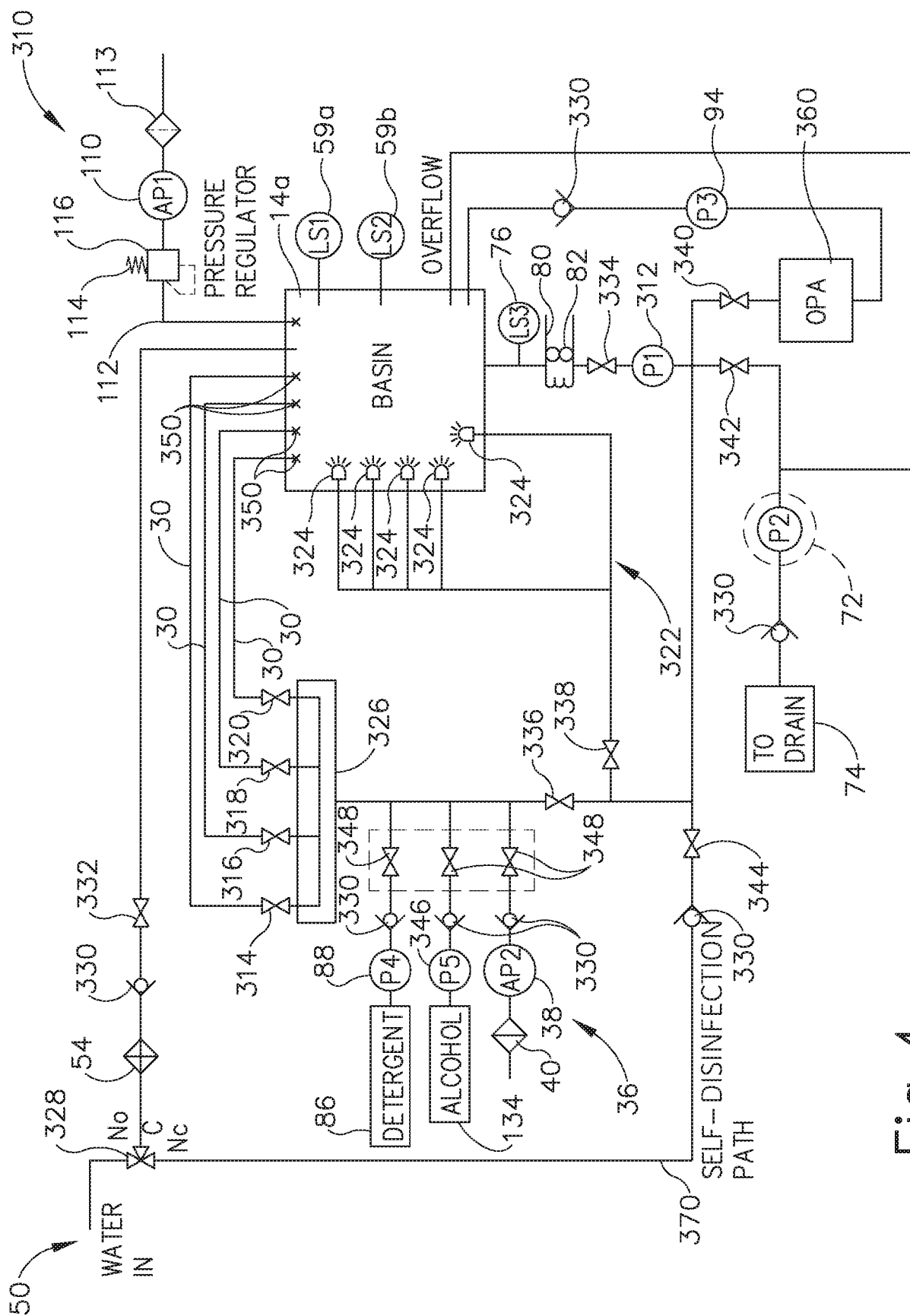


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3. 5.



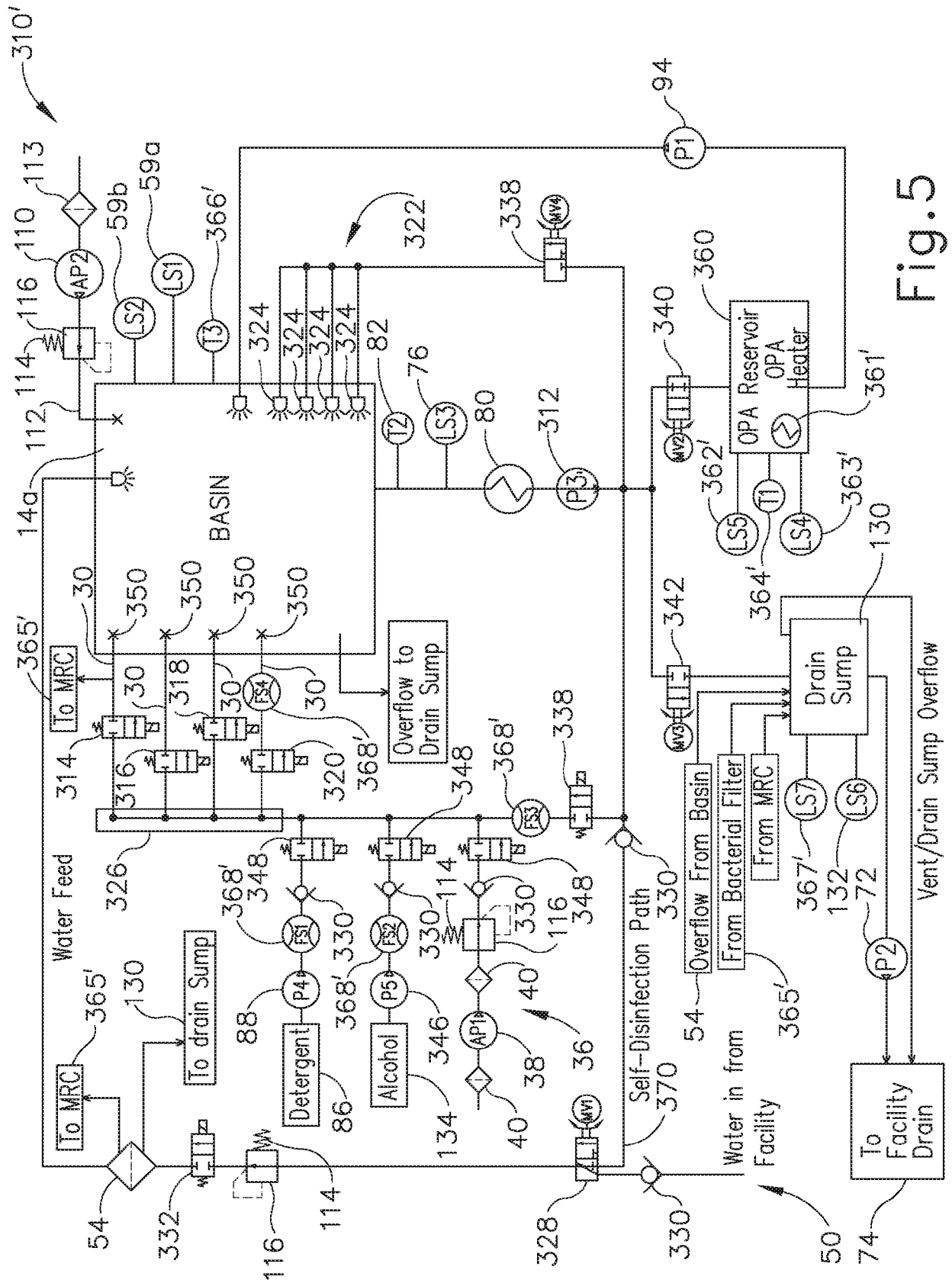


Fig.5

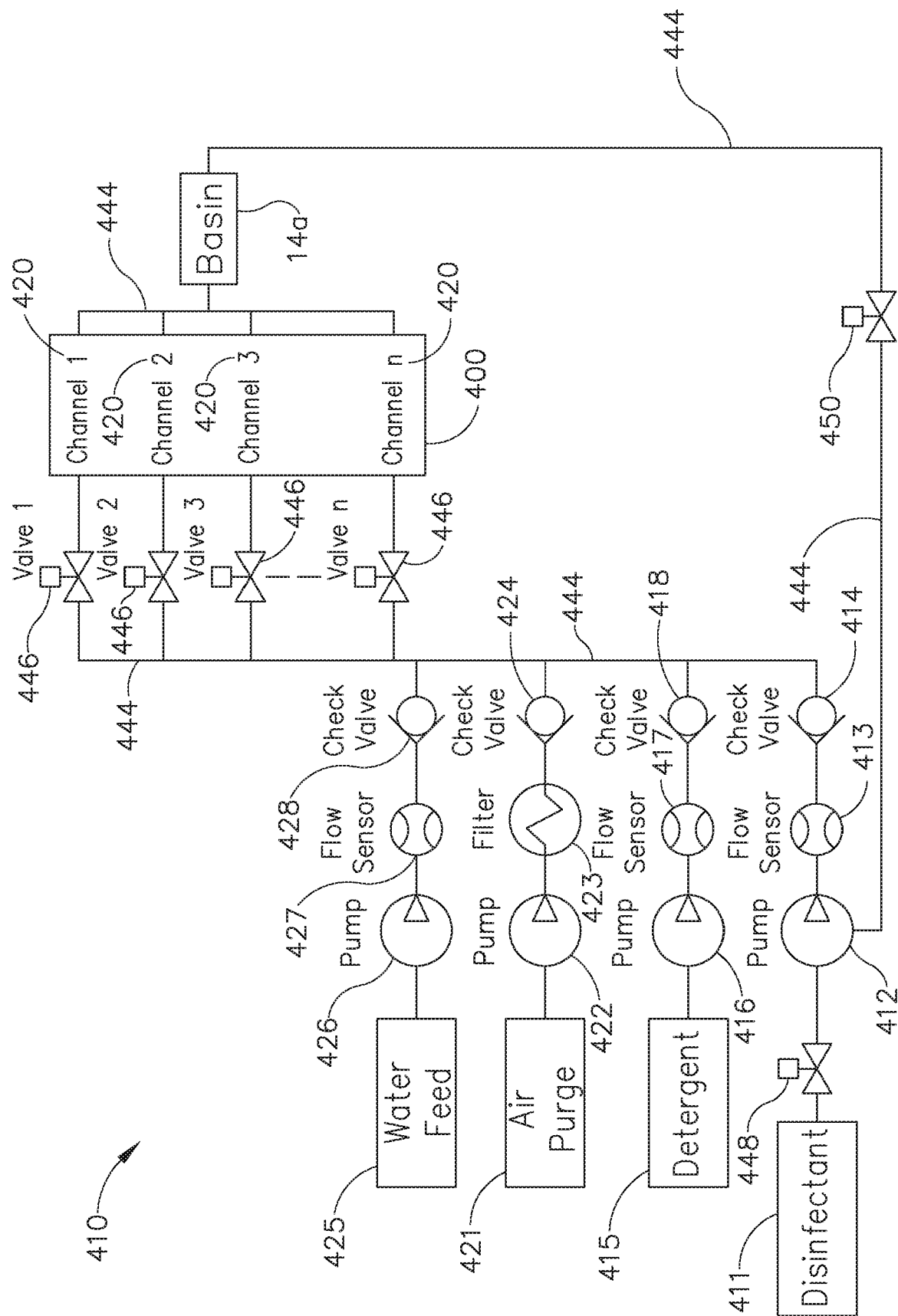


Fig. 6

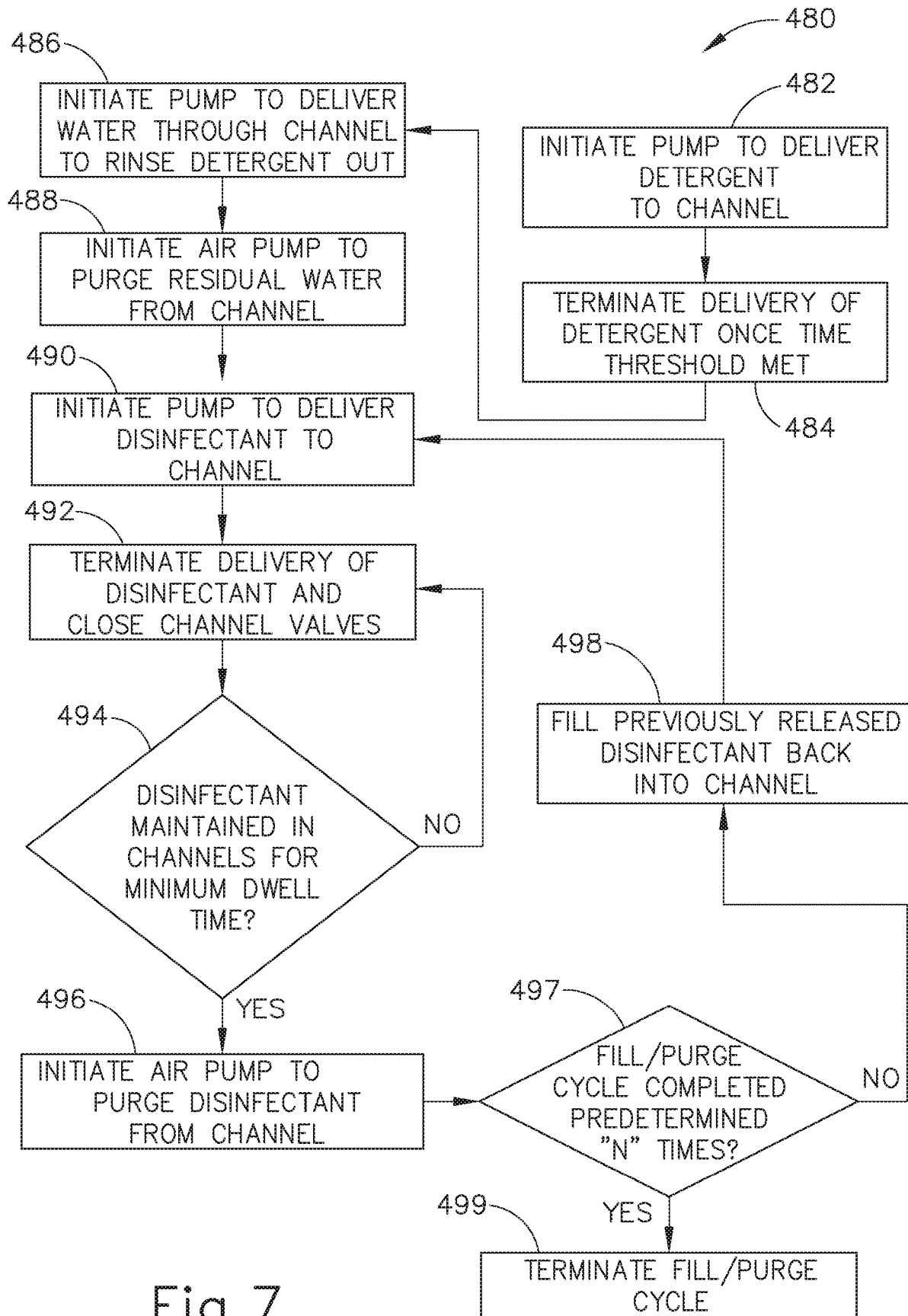


Fig.7

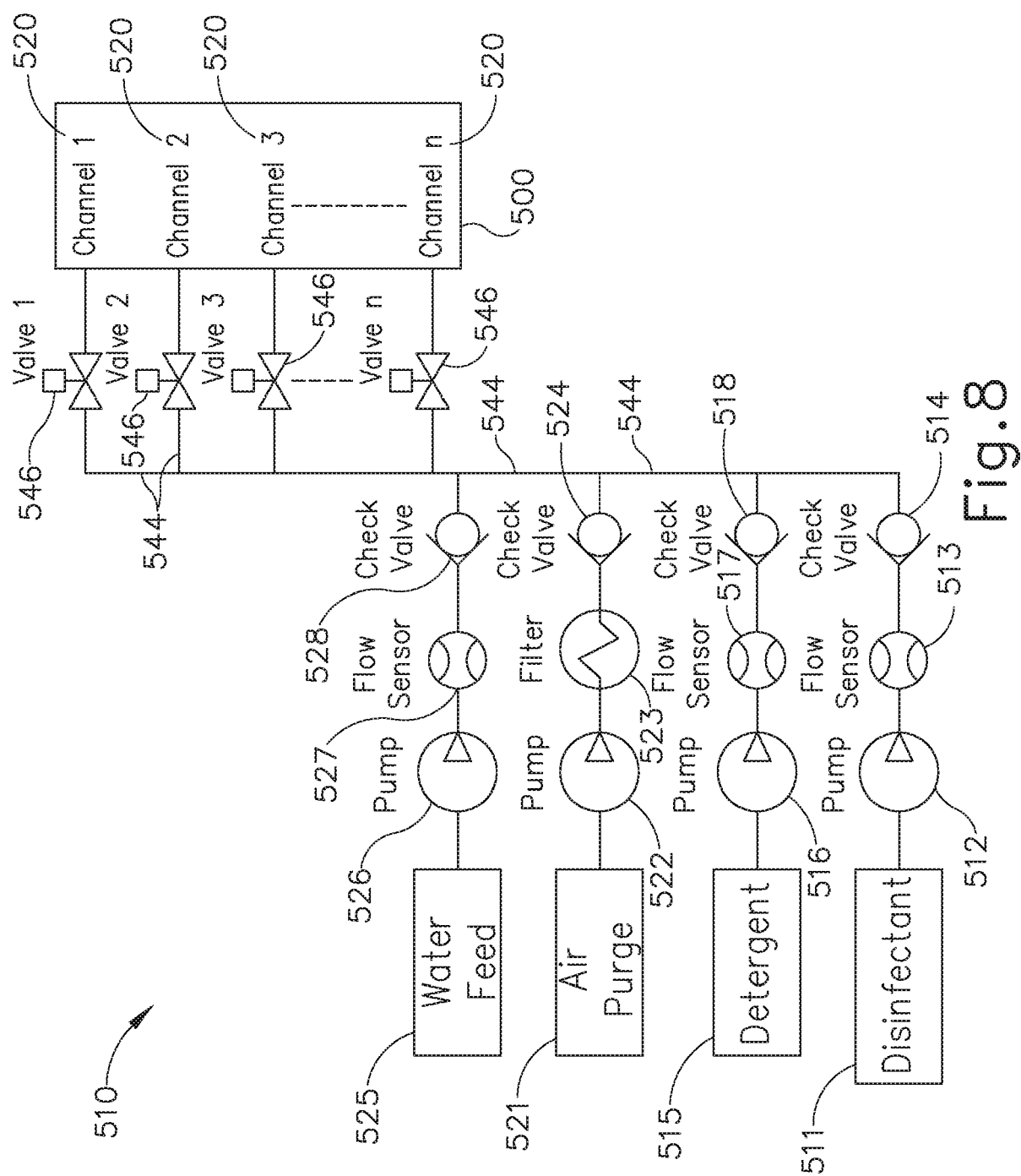


Fig. 8

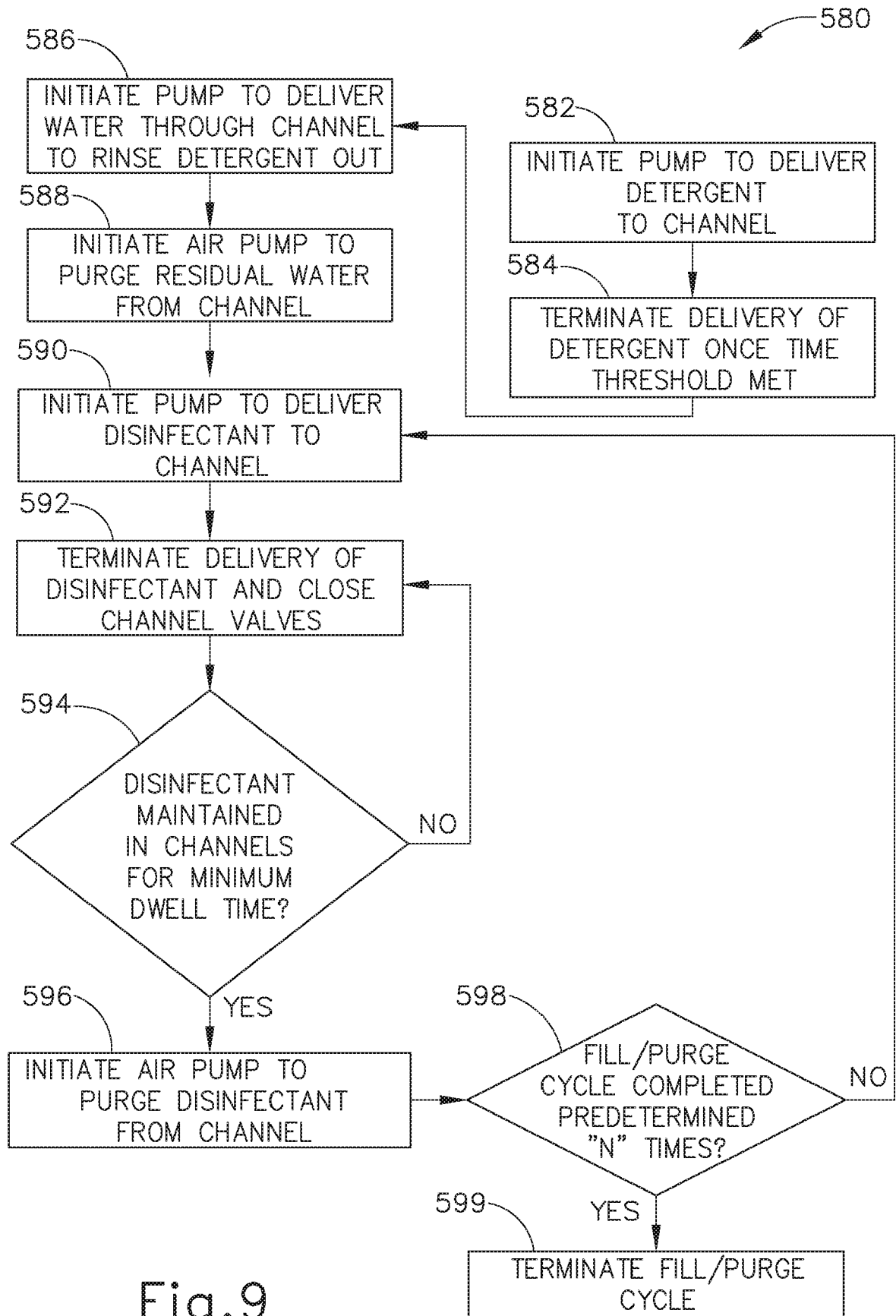


Fig.9



## EUROPEAN SEARCH REPORT

Application Number  
EP 18 19 4289

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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 6 585 943 B1 (SANFORD BILL R [US] ET AL) 1 July 2003 (2003-07-01) * column 4, lines 34-37,41-45,53-61 * * column 5, lines 10,50 - line 54 * * column 11, lines 12-17,31-36 * * column 12, line 6 - line 12 * * column 12, line 19 - column 13, line 10 * * column 13, lines 42,43,58 - line 65 * * column 14, lines 1-10,13,14 * * figure 1 *	1-20	INV. A61B1/12 A61L2/18 A61L2/24
X	US 2009/062610 A1 (WILLIAMS HAL [US]) 5 March 2009 (2009-03-05) * paragraphs [0023], [0038], [0060] * * paragraph [0075] - paragraph [0077] * * paragraphs [0081], [0082], [0084], [0085] * * paragraphs [0088], [0089], [0092], [0093] * * paragraphs [0098], [0099] * * figure 2 *	1-20	TECHNICAL FIELDS SEARCHED (IPC) A61B A61L
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 15 January 2019	Examiner Doyle, Aidan
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
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EP 18 19 4289

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EDP file on  
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15-01-2019

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